EXHIBIT 116

(EXHIBIT FILED UNDER SEAL)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION	**Lead Case No. 3:21-cv-03825-VC**
THIS DOCUMENT RELATES TO: **All Actions**	

Rebuttal Expert Report of Dr. T. Kim Parnell

March 1, 2023

<u>Highly Confidential – Subject to Protective Order</u>

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I. QUALIFICATIONS

1. I am a trained Professional Mechanical Engineer (PE) licensed in the State of California. I hold three academic degrees: a B.E.S. in Engineering Science (with Highest Honors) from the Georgia Institute of Technology in 1978, followed by a M.S. and a Ph.D. in Mechanical Engineering from Stanford University in 1979 and 1984, respectively.

2. I am an ASME Fellow and an IEEE Senior Member. ASME is the American Society of Mechanical Engineers and IEEE is the Institute of Electrical & Electronics Engineers. These are the primary professional organizations for Mechanical and Electrical Engineering. There is significant cross-over in terms of combination electro-mechanical devices that need a multi-disciplinary background. I am a Board Member of IEEE-CNSV (Consultants' Network of Silicon Valley). I am also a member of IEEE-EMBS (Engineering in Medicine & Biology), IEEE-CE (Consumer Electronics), IEEE-VTS (Vehicular Technology Society), and IEEE-EPS (Electronics Packaging Society), which focuses specifically on the electronics industry and electronic components, manufacturing, and testing. I have served as an elected officer for several of these groups including as Chair of the IEEE-SCV (Santa Clara Valley) Section (the largest IEEE Section in the world with over 12,000 members in Silicon Valley), Chair of IEEE-CNSV (Consultants' Network of Silicon Valley), and Vice Chair/Treasurer of IEEE-VTS (Vehicular Technology Society). I am also a Member of ASM International (Materials Information Society) and SAE (Society of Automotive Engineers) International. I am Vice-Chair of the NAFEMS Composites Working Group (CWG) which focuses on simulation (Finite Element and other techniques) and on applications of composite materials in all industries.

3. I currently work as an independent consultant through Parnell Engineering & Consulting (PEC). I consult for high-tech industry and legal firms regarding patents, product liability, failure analysis, reliability, and product design/development issues. I have over 30 years of professional experience using and combining analysis, simulation, inspection, and laboratory measurement to understand and solve engineering problems in a variety of industries and applications. Many of my projects involve products with both electrical and mechanical components and require a multi-disciplinary approach and expertise.

4. I have studied design and ruggedization of a variety of components and systems that must withstand severe service and environmental conditions in service such as medical devices, medical equipment, portable electronic devices, cell phones, and laptops. This experience further includes analyses of materials and material behavior, including elasticity, flexibility, and impact, in addition to deep technical experience with composites, polymeric materials, and manufacturing methods.

5. I have direct experience with manufacturing in multiple industries during my consulting career. This work began in the 1980s and includes various projects up to the present time. These applications include consumer electronics, biomedical, medical device, automotive, petrochemical, paper, metal forming, specialty materials and others. Equipment at issue often involves injection molding, metal forming, stamping, and machining, semiconductor packaging, pipelines and piping components, pressure vessels, sensors and control systems.

6. I began my professional career in 1978 at Bell Laboratories in Indianapolis, Indiana after graduation from Georgia Tech. I was a Member of Technical Staff (MTS) at Bell Labs with a focus on design and development of telephone electro-mechanical components. I worked at Bell

Labs before and during my Stanford M.S.M.E. degree, and Bell Labs supported me financially for that degree and I remained on staff.

7. At Bell Labs, I worked specifically on keyboard and keypad applications and new design concepts for telephone sets. I built prototypes, studied, tested, and developed designs utilizing stainless steel domes (caps), silicone rubber domes, piezoelectric polymers, and other novel technologies to simplify design, manufacturing, and assembly in addition to improving reliability. Environmental damage and reduced reliability were of particular concern for telephone sets, especially if the use environment was challenging (dirty, particulates, etc.). The need to develop more reliable and robust keypads and keyboards for these applications motivated this development and the focus on bringing innovative new technologies to the customers in the field. There was a strong emphasis on life-testing at both the component and the system level for all telecom related equipment. Reliability and robust design always represented a central focus throughout Bell Labs and the Bell System. These designs were developed with a keen sense of the importance of the manufacturing and assembly process to the in-service equipment.

8. I took a leave of absence from Bell Labs and returned to Stanford in 1980 to pursue a Ph.D. in Mechanical Engineering, which I completed in 1984. My work on keyboard and keypad concepts utilizing domes and snap-through buckling behavior for providing a tactile response motivated my Ph.D. research work at Stanford.

9. After Stanford, I then joined SST Systems, Inc. as a Principal Engineer from 1984-1986. In 1986, I joined Failure Analysis Associates, Inc. as a Senior Engineer in the Mechanics and Materials Department. I was promoted to Managing Engineer in 1990. I worked on a wide range of projects as a consultant including aspects such as product failures, product design, and

medical device development. The company went public in 1990 as “The Failure Group,” but then changed its name to Exponent in the mid-1990’s. In 1998, I was promoted to Senior Managing Engineer at Exponent. After 13 years at Exponent, I left to explore the medical device field and joined Rubicor Medical, Inc. in 1999 as Director of Research & Development.

10. When I left Rubicor in 2000, I started offering independent engineering consulting services under Parnell Engineering & Consulting (PEC). I have been an independent consultant from 2000 to the present. During that time, I also worked for MSC Software (2006-2010) in Product Management for finite element simulation software products, consulting, and customer applications.

11. At MSC Software, I was a Senior Manager in the Product Management group, where I contributed in areas such as the User Experience, testing and evaluation of nonlinear simulation tools, and also training. I was recognized as an expert in applications of nonlinear finite element analysis to industry products and challenges. I was an MSC Software technical staff member from 2006-2010, and I consulted with MSC Software extensively from 2000-2018.

12. I was a full-time member of the Mechanical Engineering faculty at Santa Clara University from 2010-2012 and taught classes in Manufacturing, Material Science, Mechanical Design, Finite Element Analysis (FEA), Composite Materials, and Kinematics & Mechanisms. During this time, I served as the Faculty Advisor for several Senior Design Projects. These “real world” Capstone Design Projects encompassed design, system integration, and manufacturing aspects, and provided the students with a full product development experience. I also taught graduate courses in Mechanical Engineering at Stanford University from 1995-1996. I have delivered numerous invited presentations, short-courses, and seminars on a range of technical

topics to professional organizations and companies. Some of the topics include Mechanical Design for Reliability (MDfR) courses tailored to specific types of products and industries, and Medical Device Technology. I also taught several courses involving the application of simulation and analysis tools and how to better utilize simulation in the design cycle to reduce prototypes, shorten development time, and improve product reliability.

13. My project work includes studies for a broad range of consumer products, equipment, and manufacturing methods. Over the years, I have also consulted in the areas of structural mechanics, shock and vibration sensitivity, fracture and fatigue, robust design, and finite element analysis of structures. My practice often encompasses design, failure analysis, forensic investigation, root cause analysis, and reliability issues. My expert work often involves similar issues and often intellectual property matters. Keypad and keyboard concepts include mechanisms, interfaces, and physical design along with volume manufacturing considerations. Recent laptop patent cases involved keyboard technology for moisture resistance, and a laptop display mounting concept to allow the screen to fully pivot or rotate. I also studied enclosures for portable electronic devices for ruggedization and resistance to adverse environments. Hands-on inspection, disassembly, and sometimes destructive evaluations are typical components of projects for portable electronics and medical products.

14. A more comprehensive record of my professional background and technical qualifications is reflected in my curriculum vitae, which is attached hereto as Attachment A. A list of my expert engagements is also included in my curriculum vitae.

15. My opinions and conclusions in this report are based on my years of professional experience in mechanical engineering, failure analysis, and other work in medical devices, medical

instruments, consumer electronics, and other sophisticated technology devices. I have relied upon the documents and testimony listed in Attachment B (as well as the materials cited in the text and footnotes of this report). I reserve the right to supplement or amend my report as new information becomes available.

16. I am not currently and have not previously been employed by Larkin Community Hospital, Franciscan Alliance, Inc. or King County Public Hospital District No. 1, d/b/a Valley Medical Center (collectively, "Hospital Plaintiffs").

II. PRIOR TESTIMONY AND PUBLICATIONS

17. My current *Curriculum Vitae* is attached to this report at Attachment A, and includes a list of prior testimony over the past four years, and a list of all publications I have authored or co-authored during the past ten years.

III. ENGAGEMENT AND COMPENSATION

18. Counsel for the Hospital Plaintiffs retained me to provide my independent and objective analysis of several engineering issues in this case, and more specifically to rebut the report submitted by Dr. Robert D. Howe in this action, dated January 18, 2023 (the "Howe Hospital Report"),[1] which was purportedly in opposition to the reports of a number of experts who submitted opening reports on behalf of the Hospital Plaintiffs.[2] This report sets forth my opinions about which I may testify if called as a witness at the trial of this action.

19. On January 18, 2023, I also submitted an expert report in *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.,* Case No. 3:21-cv-03496-VC (N.D. Cal.) (the

[1] Expert Report of Dr. Robert Howe, *In Re: Da Vinci Surgical Robot Antitrust Litigation,* Lead Case No. 3:21-cv-03825-VC, dated January 18, 2023 (hereinafter "Howe Hospital Report").

[2] Howe Hospital Report ¶ 7.

"SIS action") opining on the several engineering issues in that case,[3] and more specifically to oppose the opening report submitted by Dr. Robert D. Howe in that action, dated December 2, 2022.[4]

20. The materials that I considered in forming my opinions in this rebuttal report are listed in Appendix B.

21. I am being compensated for my time spent in this matter at an hourly rate of $600 / hour. If asked to testify in this action, I will be compensated at the rate of $600 / hour for deposition testimony and $600 / hour for testifying at trial. My compensation does not depend in any way on the outcome of this action or the SIS action.

IV. SUMMARY OF OPINIONS

22. Traditional laparoscopic instruments are routinely repaired, and in my opinion, EndoWrists may be similarly repaired. Dr. Howe opines that "there are significant differences between EndoWrist instruments and traditional laparoscopic instruments, and that these differences contribute to EndoWrist instruments having a shorter useful life than traditional laparoscopic instruments." Howe Hospital Report ¶ 16; *see also id.* ¶¶ 34-47. However, in my opinion, the elements of the EndoWrist identified by Dr. Howe do not preclude repair. Both Si and Xi EndoWrists are based on relatively simple components and engineering principles, and the specific design is now decades old. Actual data and basic engineering principles demonstrate that any differences between EndoWrist instruments and traditional laparoscopic instruments do not (a) justify the use limits imposed by Intuitive's use counter, or (b) preclude repair.

[3] Expert Report of Dr. T. Kim. Parnell, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.,* Case No. 3:21-cv-03496-VC, dated January 18, 2023.

[4] Expert Report of Dr. Robert Howe, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.,* Case No. 3:21-cv-03496-VC, dated December 2, 2022.

23. Dr. Howe opines that "although Rebotix, Restore, and SIS refer to the 'reset' service Rebotix provides as a 'repair,' Rebotix simply devised a method that intercepts communication between the robot and the instrument in order to circumvent the usage limits implemented in each EndoWrist instrument, without adequately addressing the effects of wear and tear that accrue during instrument usage." Howe Hospital Report ¶ 19 (footnote omitted); *see also id.* ¶¶ 48-51. To the contrary, the Rebotix repair process that was initially relied on by SIS and Restore is much more comprehensive than just a reset of the use counter, and fully addressed the effects of wear and tear on EndoWrist instruments (including those outlined in the Howe Hospital Report ¶¶ 73-79) such that it was proper to repair and return those instruments to hospitals for additional uses. My opinion is based in large part, and as set forth in detail below, on my personal observations of the repair procedure during my visit to Rebotix on August 10, 2021.

24. Dr. Howe contends that (a) Intuitive has "conducted rigorous testing and identified a maximum use limit for EndoWrists," and "the maximum use limit ensures that instruments perform safely and reliably"; (b) Intuitive testing "demonstrates that [EndoWrist] instruments can only be reliably used a limited number of times" based on "significant wear and tear during their prescribed useful life"; and (c) "Intuitive Designs and Tests its EndoWrist Instruments to Reliably and Safely Perform Over a Set Number of 'Lives.'" Howe Hospital Report ¶¶ 8, 13, 17-18, 52-72. To the contrary, the Intuitive use counter has many deficiencies, is not an effective means of preventing instrument failure, and does not ensure proper operation of the EndoWrist. In fact, the use counter fails to account for actual usage or wear and tear (*see* Howe Hospital Report ¶¶ 18-19), even though Intuitive has the means to account more accurately for these factors.

25. Dr. Howe's negative opinions about Restore's and SIS's reliance on Rebotix processes and Rebotix-supplied information (Howe Hospital Report ¶¶ 23; *see also id.* ¶¶ 10, 11, 81) ignore the respective functions of these companies in the instrument repair industry, and that Rebotix provided these companies with documentation concerning its safety protocols and the testing performed by Rebotix.

26. Dr. Howe criticizes "Rebotix's 'EndoWrist Service Procedure[,]'" "Rebotix's risk management activities with respect to extending lives of EndoWrist instruments[,]" and "Rebotix's life testing[.]" Howe Hospital Report ¶¶ 20-22, *see also id.* ¶¶ 80-136. However, (a) my own review of the underlying Rebotix documentation, (b) my personal inspection at the Rebotix facility and (c) my review of the Rebotix service procedure demonstrates that Rebotix did in fact sufficiently and reasonably support the safety and reliability of its EndoWrist repair process. Dr. Howe misunderstands the Rebotix service procedure, does not address detailed underlying documentation, and makes unfounded assertions about potential safety concerns. In my opinion, the Rebotix repair procedure for EndoWrists is thorough and well-documented. The Rebotix risk management activities are robust, and its life testing proves that EndoWrists are suitable for repair beyond Intuitive's use limits, which are set by Intuitive's marketing personnel, as discussed below. Moreover, a careful review of the Iconocare repair process, with which Dr. Howe has identified no deficiencies, shows substantial overlap and commonality with the Rebotix repair process.

27. Dr. Howe opines that "Intuitive's position that it could potentially develop robust EndoWrist refurbishment procedures does not mean that Rebotix's resetting procedures were adequate." Howe Hospital Report ¶ 24, *see also id.* ¶¶ 137-139. To the contrary, Intuitive's efforts to develop a refurbishment process demonstrate that the profit from EndoWrist replacement

compared to the profitability of selling new EndoWrists was the principal reason for this decision. Similar to its initial marketing-based decision to limit EndoWrist to a number of uses, Intuitive's driving reason for not adopting the refurbishment procedure was to maximize profits, not due to any underlying engineering issues. Also note that the contemplated Intuitive refurbishment program planned for extensive replacement (not repair) of EndoWrist components and this inflated costs. The Intuitive refurbishment program was based on worst-case assumptions, and did not use a careful inspection of the instrument to assess the needed repairs or inability to repair a specific submitted EndoWrist.

28. Dr. Howe opines that "the Iconocare Process is likely to produce safer and more reliably-remanufactured instruments than the Rebotix Process," and "that the risk management and life data submitted to the FDA for the Iconocare Process is significantly more robust than the risk management and life testing data Rebotix had access to in connection with the Rebotix Process." Howe Hospital Report ¶¶ 26-27; *see also id.* ¶¶ 140-158. In fact, Dr. Howe's endorsement and acceptance of the Iconocare Process for producing safe and reliable instruments, and of the Iconocare risk management and life testing procedures, demonstrates that similar or even more robust aspects of the Rebotix procedure, risk management, and life testing result in safe and effective repaired instruments. Moreover, the differences he identifies between the Iconocare and Rebotix processes are minor, and in fact demonstrate that any purported deficiencies in the Rebotix process could be easily improved absent the Intuitive efforts to interfere with the Rebotix process development.

29. Dr. Howe further opines that "there are significantly greater safety risks created by resetting an EndoWrist usage counter multiple times[.]" Howe Hospital Report ¶ 27; *see also id.*

¶¶ 159-164. Dr. Howe lacks reliable data to make such a claim, including because Intuitive intentionally chooses not to test beyond its marketing-determined use limits. Moreover, the actual RMA data from the field in fact demonstrates that EndoWrists fail at a similar rate with repeated uses. Indeed, EndoWrists often fail even before the use counter is fully decremented. Intuitive's inspection and analysis of the failures has shown that many are due to misuse or mishandling (in a variety of ways) before 10 uses.

30. Finally, Dr. Howe opines that "the procedures performed by Restore to 'service da Vinci surgical systems contain significant deficiencies that do not allow proper maintenance or repair of da Vinci surgical robots . . . ." Howe Hospital Report ¶ 28; *see also id.* ¶¶ 165-196. In my opinion, although there were certain limitations to Restore's service offerings, Restore demonstrated the ability to provide some maintenance and repair services for the da Vinci robot.

V. TRADITIONAL LAPAROSCOPIC INSTRUMENTS ARE ROUTINELY REPAIRED - ENDOWRISTS CAN BE SIMILARLY REPAIRED

31. The Hospital Plaintiffs allege that "EndoWrists and traditional instruments are similar in many ways, including as to their surgical ends,"[5] and that "EndoWrists are in many respects nearly indistinguishable from manually operated surgical tools," in that "[b]oth are made from medical grade materials, such as stainless steel and composites" and "that their surgical ends are nearly identical."[6] I disagree with Dr. Howe's claims that "there are a number of features that are unique to EndoWrist instruments as compared to those in traditional laparoscopic instruments" that render EndoWrist instruments incapable of repair.[7] The critical factor in the Rebotix and SIS

[5] Consolidated Amended Class Action Complaint ¶ 109, *In Re: Da Vinci Surgical Robot Antitrust Litigation,* Lead Case No. 3:21-cv-03825-VC, dated September 10, 2021 ("Hospital Complaint").
[6] Hospital Complaint ¶ 112.
[7] Howe Hospital Report ¶ 34.

repair procedure is a careful inspection of each incoming EndoWrist to determine if it is suitable for repair, or if it should be rejected as a repair candidate. *See* Section VI.B, below.

A. <u>Traditional laparoscopic instruments and EndoWrists have many similarities.</u>

32. Both traditional laparoscopic instruments and EndoWrists are designed to be used in minimally invasive surgeries. The distal ends of laparoscopic instruments and the distal ends of EndoWrists are virtually indistinguishable, and each instrument is expected to perform the same function in a surgery. For example, a traditional laparoscopic scissor and an EndoWrist scissor are both designed to cut tissue. They perform essentially the same function:

> Page 95
> MR. ERWIG: Q. Mr. DeSantis, one of the
> instruments that's described here is scissors; right?
> A Yes.
> Q And your understanding of the function of
> scissors in surgery is to cut tissue; right?
> A Yes.
> Q And the scissors on the end of the EndoWrist,
> those are designed to cut tissue; right?
> A Yes.
> Q And the scissors on the end of traditional
> laparoscopic instruments, those are designed to cut
> tissue as well; right?
> A Yes.
> Page 96
> Q And what it means for something to be similar
> in terms of intended use is that those two things are
> performing essentially the same effect in surgery;
> right?
> A Yes.[8]

[8] DeSantis depo. (*Rebotix*) tr., 95:13 – 96:5.

33. Intuitive's own initial 510(k) submissions and its understanding of EndoWrists confirm the similarities between EndoWrists and traditional laparoscopic instruments. The working ends and elements of the EndoWrists are "essentially identical in size and shape to the predicate devices" – laparoscopic instruments.[9] And the EndoWrists themselves "are essentially identical in terms of shape, size, function, and tissue effect" to the instruments that Intuitive identified as predicate devices in its initial 1999 510(k) submission to the FDA.[10]

B. <u>Traditional laparoscopic instruments are routinely repaired</u>

34. Traditional laparoscopic instruments occasionally experience failures as they are used.[11] The scissors at the end of traditional laparoscopic devices become dull and are eventually not sharp enough to precisely cut tissue during surgery.[12] Graspers become misaligned or unable to grasp tissue with sufficient force.[13] And needle drivers loosen such that they cannot hold a needle as tightly as required for precise use during surgery.[14]

35. Hospitals and the surgeon users evaluate wear on these instruments by assessing whether they are performing their required function in surgery.[15] Hospitals will assess a traditional instrument both in a pre-operative inspection and during an actual surgery. If an instrument is not performing its function appropriately, hospitals will replace the instrument during the surgery and evaluate it for potential repair. It is a standard practice of hospitals to repair instruments used in traditional laparoscopic surgeries.[16] In those repairs, the traditional instruments are cleaned,

[9] Mark Johnson depo. (*Rebotix*) tr., 28:12-17.
[10] *Id*. at 31:8-23.
[11] DeSantis depo. (*Rebotix*) tr., 134:21-23.
[12] *Id*. at 134:24 – 135:1.
[13] *Id*. at 135:2-5.
[14] *Id*. at 135:6-8.
[15] Harrich, (*Rebotix*) depo. tr., 36:5-8.
[16] *See*, e.g., Donovan (*Rebotix*) depo. tr., 29:14-18, Harrich (*Rebotix*) depo. tr., 32:17-33:3.

aligned and bent into shape, sharpened, and inspected under a microscope.[17] The continued reuse and repair of those instruments allows the hospital to continue to use them for surgeries.[18] And evidence I have reviewed indicates that hospitals will not repair or service a product if that repair or service could make the repaired/serviced product unsafe for use.[19]

36. Bob Overmars, the president of BPI Medical, a company that has repaired "tens of thousands" of laparoscopic instruments, testified that traditional laparoscopic instruments can be used "dozens to hundreds" of times before being sent in for repair.

> Q. One of the instruments you indicated you repaired is laparoscopic instruments; is that right?
> A. That's correct.
> Q. When did you first start repairing laparoscopic instruments?
> A. Over 20 years ago.
> Q. What is your best estimate of how many laparoscopic instruments BPI Medical has repaired?
> A. Tens of thousands
> ...
> Q. Is one of the laparoscopic instruments that BPI Medical repairs the Deknatel Snowden-Pencer Diamond-Touch?
> MR. FOLGER: Objection to form.
> BY MR. LYON:
> Q. I didn't hear your response.
> A. Yes, we do.[20]

37. SIS similarly has decades of experience repairing laparoscopic instruments.[21]

[17] Harrich depo. (*Rebotix*) tr., 33:5-12.
[18] *Id*. at 33:5-16.
[19] *Id*. at 26:9-12.
[20] Overmars depo. (*Rebotix*) tr., 96:14-97:10.
[21] Conversations with G. Posdal.

38. Laparoscopic instruments in need of repair can suffer from unintuitive motion, insufficient grip force, dull or damaged scissor blades, and worn or damaged cables. Those failure modes are common in laparoscopic instruments in need of repair. And a hospital makes the determination to send an instrument in for repair based on the wear it has experienced and its inability to perform functions in surgery.

Q. How many times is a typical laparoscopic
instrument used before it's sent to you for repairs?
A. It could be dozens to hundreds.
Q. What determines if it's dozens or hundreds?
A. There will be lack of grip of the
instrument jaws. There will be dull scissors.
There will be broken or failed components.
Q. Are these some of the problems you see in a
laparoscopic instrument in need of repair?
A. Absolutely.
Q. Is unintuitive motion one of the problems
you commonly see in a laparoscopic instrument in
need of repair?
A. Correct.
Q. Is insufficient grip force one of the
problems you typically see in a laparoscopic
Page 99
instrument in need of repair?
A. Correct.
Q. Is dull or damaged scissor blades one of
the problems you typically see in a laparoscopic
instrument in need of repair?
A. Correct.
Q. Is worn or damaged cables one of the
problems you typically see in a laparoscopic
instrument in need of repair?
MR. FOLGER: I'll just object to the form.
BY MR. LYON:
Q. Again, I didn't get your answer. Remember

> to pause. Could you repeat your answer for me. The court reporter may have got it, but I didn't hear it.
> A. Correct.
> Q. Are these the sort of prob -- withdrawn. Do you consider these common problems in laparoscopic instruments that you repair?
> A. Yes.[22]

39. Mr. Overmars and his company have years of experience with both EndoWrists and traditional instruments. In comparison to traditional instruments, EndoWrists are more robust and well-made.

> How would you compare how well made EndoWrists are relative to traditional laparoscopic instruments?
> MR. FOLGER: I'll still object to the form.
> Page 102
> A. In our 25 years of experience of repairing endo laparoscopic instruments, the EndoWrist is built like a Hummer and the majority of all other laparoscopic instruments are like Ikea. The Intuitive EndoWrist is much more robust, much more uniquely designed, and just simply a way better, longer lasting instrument than a traditional laparoscopic instrument.[23]

40. Mr. Overmars' testimony that EndoWrists are "more robust" and "longer lasting" than traditional laparoscopic instruments was borne out by my own observations at Rebotix's facility, and my subsequent and independent examination of EndoWrists provided to me by counsel. The construction of the EndoWrist was more durable than the construction of similar

[22] Overmars depo. (*Rebotix*) tr., 98:10-99:20.
[23] *Id.* at 101:22-102:8.

laparoscopic instruments. Therefore, I would expect that EndoWrists could potentially withstand more uses between repairs than traditional laparoscopic instruments. The key requirement is careful inspection and screening for any damage.

C. <u>EndoWrists can be routinely repaired in the same manner as traditional laparoscopic instruments.</u>

41. EndoWrists have similar failure modes as traditional laparoscopic instruments. For example, like with laparoscopic scissors, the scissors on EndoWrists also become dull over time and are eventually unable to cut tissue.[24] And similarly, the graspers on an EndoWrist become misaligned, and the needle drivers are not able to hold a needle as tightly as required for reliable surgical use.[25]

42. Hospitals also inspect EndoWrist instruments prior to surgery to determine whether there are any issues with the EndoWrist. And failure modes on EndoWrists, just like on traditional laparoscopic instruments, are obvious.

> Page 40
> Q. Does your hospital undertake any inspection
> efforts of an EndoWrist before it's used in a surgery?
> A. Absolutely.
> Q. What process does your hospital undertake to
> inspect an EndoWrist from Intuitive before it's used
> in a surgery?
> A. So the inspection process will start in
> central sterile processing. There is multiple steps
> on processing and packaging those instrumentations,
> protecting the tips on them.
> Once they're packaged, sent through sterile
> processing, they come into the room. The scrub tech,
> when they open the trays, will examine them on the

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[24] DeSantis depo. (*Rebotix*) tr., 134:24-135:1, 213:22-25.
[25] *Id*. at 135:2-8, 272:24-273:1.

> field, make sure that the jaws are open and close,
> that the -- you know, everything is clean, that there
> is no dried blood, that the ports are working.
> And then the first assist will do that also.
> Page 41
> Q. Are traditional laparoscopic instruments used
> in nonrobotic surgeries inspected in the same way as
> the EndoWrists are?
> A. Yeah, there is a little bit of different
> process. Some of the robotic instruments are a little
> bit more complicated with their flushing ports or how
> they're loaded, but, yes, all of our instruments are
> inspected.
> Q. Do the EndoWrists sometimes fail the
> inspection?
> A. Yes.[26]

43. The failure modes on EndoWrists that hospitals detect before the use counter has expired include misalignment of graspers, frayed cables, chipped tracks, or dull scissors.

> Page 41
> Q. What are some of the ways an EndoWrist might
> fail before it reaches its maximum number of uses?
> A. So -- okay. So they -- the teeth might
> misalign. They'll get shifted so that they don't
> close completely lined up. They'll get a little bit
> offset.
> The -- there is like wires, the bands. They
> fray, so there may be a frayed wire on them.
> Page 42
> They roll on a roller, a track, and that
> track may get chipped or the wire may come over the
> top of the roller. It's like a pulley. Or the
> scissors are dull and so they'll gnaw through the
> tissue instead of making a clean cut.[27]

[26] Harrich depo. (*Rebotix*) tr., 40:9 – 41:11
[27] *Id.* at 41:18 – 42:5.

44. Each of these potential failures is addressed through the Rebotix repair procedure that Rebotix initially performed for SIS, and that SIS was planning to perform in-house, as described below (*i.e.*, the "Rebotix repairs" or "Rebotix procedure"). The Rebotix repair process does not make any of these failures more likely.

D. The "Unique" Elements of the EndoWrist Identified by Dr. Howe Do Not Preclude Repair

45. Dr. Howe discusses several differences between traditional laparoscopic instruments and EndoWrists that, in his opinion, make EndoWrists unsuitable for repair.[28]

46. First, Dr. Howe asserts that the motor interface of the EndoWrist produces unique constraints and failure modes.[29] Specifically, Dr. Howe asserts that the pins on input pulleys in the motor interface may slip or shear. He also asserts that bearings that enable low friction motion can fail.

47. Second, Dr. Howe asserts that "[b]ecause EndoWrist instruments are driven by motors under computer control, they are also subject to high forces due to collisions that are not present for manual instruments."[30]

48. Third, Dr. Howe asserts that the cable drives in EndoWrists "are more complex to design," may result in faster failures of the instrument, and are unsuitable for repair.[31] As support, Dr. Howe cites to a general mechanical engineering design textbook for broad guidelines (not specific to the EndoWrist).[32] An excerpt from the quoted text does stress that: "…In view of the

[28] Howe Hospital Report ¶¶ 34-47.
[29] *Id.* ¶ 36.
[30] *Id.* ¶ 38.
[31] *Id.* ¶¶ 41-42, 43-46.
[32] *Id.* at fn. 33.

fact that the life of the wire rope used over sheaves is only finite, it is extremely important that the *designer specify and insist that periodic inspection, lubrication, and maintenance procedures be carried out during the life of the rope*."[33] (emphasis added). This specific guidance for inspection and maintenance is an important part of the Rebotix EndoWrist repair process, as described later in this report.

49. Fourth, Dr. Howe asserts that the cleaning and sterilization cycles that EndoWrists are subjected to are "particularly detrimental to continuing reliable operation" and that "[t]he corrosion that results from reprocessing is well-known to degrade wire rope drives."[34]

50. For each of these differences to make an EndoWrist unsuitable for repair, they would either (1) have to be overlooked or ignored in the repair process, or (2) require testing to confirm that repairs are not feasible or possible.

1. <u>The Rebotix repair procedure takes any failures in the motor interface into account.</u>

51. In the Rebotix repair process, each EndoWrist is inspected when it is received for repair. If it is discovered that an EndoWrist has any of the motor interface issues identified by Dr. Howe (pin slipping/shearing or failed bearings), Rebotix will not repair that instrument. For example, pin slipping or shearing results in the instrument being unable to move or difficulty in mounting the EndoWrist to the da Vinci robot. Similarly, failed bearings could result in the instrument being unable to adequately move the cables and/or roughness in the motion. Those

33 Richard G. Budynas and J. Keith Nisbett, *Shigley's Mechanical Engineering Design*, Ninth Edition, McGraw-Hill, New York, 2008, Chapter 7, pp. 919-921.

34 Howe Hospital Report ¶¶ 41-42.

issues would be detected in either (a) the visual inspection of the components inside the instrument's proximal housing, or (b) in Rebotix's cable tensioning procedure.

52. Further, there is no evidence that suggests that any of these failures are more likely to occur after inspection and repair of an instrument, in accordance with the Rebotix process. As part of outgoing instrument evaluation, it is verified that all parts of the motor interface are functioning as expected and that there are no issues that would prevent the instrument from functioning properly.

53. Moreover, any issues of this type are regularly encountered and easily addressed in surgery. For example, the consequence of slipping or shearing of pins would be unintuitive motion, or difficulty mounting the EndoWrist to the da Vinci robot. Similarly, the failure of bearings that enable low friction motion would lead to excessive input torque requirements, input response that is rough, and unintuitive motion. Such consequences and failures are easily recognized by surgeons, and surgeons regularly and easily replace instruments when they exhibit unintuitive motion during surgery.[35]

2. <u>The Rebotix repair procedure accounts for any issues created by "collisions."</u>

54. Dr. Howe asserts that "[b]ecause the EndoWrist instruments are driven by motors under computer control, they are also subject to high forces due to collisions that are not present for manual instruments."[36] According to Dr. Howe, a surgeon can "command an instrument to move along a path that intersects with another instrument," resulting in "high forces applied to the

[35] Harrich depo. (*Rebotix*) tr., 43:20-44:19; Mahal Report ¶¶ 19, 57, 59-60; Rubach Report ¶¶ 26-27; *see also* Estape depo. tr., 69:1-73:19.
[36] Howe Hospital Report ¶ 38.

instrument, particularly the wrist."[37] Dr. Howe cites no evidence that this is a regular or even occasional occurrence, and common sense says that such would be due to the kind of user error that a skilled surgeon could easily avoid during a procedure. Indeed, neither Intuitive's simulated surgical use procedure[38] nor its test criteria[39] appear to consider instrument collisions a failure mode that requires testing.

55. More importantly, the Rebotix inspection process would identify any damage caused by any such conditions. As for direct damage to the "wrist," after an initial visual check, a Rebotix technician uses an optical microscope at high magnification to examine the tool end of the EndoWrist (the scissors, graspers, etc). As for indirect damage that might be caused to the cabling system via the wrist, during the Rebotix inspection process, the cables are carefully examined at both ends of the EndoWrist (the proximal and the distal end) under a microscope with at least 10x magnification. This process pays particular attention to the areas of cable/pulley contact and interaction. If any fraying or breakage is detected on even a single wire of the cable, the instrument is not considered a candidate for repair and will not be serviced.[40]

3. The Rebotix repair procedure resolves any issues with the cable drive system.

56. Dr. Howe asserts that the EndoWrist cable drive system makes EndoWrists unsuitable for safe repair. I disagree with this assertion. In fact, the Rebotix repair procedure first inspects and identifies any cable issues or damage that would make an instrument unsuitable for repair. During the Rebotix repair process, cables are re-tensioned to ensure that motion of the drive

[37] *Id.*
[38] *See* Intuitive-00544199.
[39] Intuitive-02066979 at 02067025-047.
[40] Greg Fiegel Conversation.

wheel corresponds directly with the appropriate response of the distal tool. As long as an EndoWrist is otherwise suitable for repair, any unintuitive response or other cable issues that might exist before the repair process are carefully eliminated with the cable tensioning step.

57. Under the Rebotix repair process, only EndoWrists that exhibit no signs of cable breakage, damage, or wear are considered for repair. There are three main components in a wire cable rope: a core, strands, and filaments.[41] Filaments are bundled into "strands" around a central "strand core."[42] These strands are then combined together into a larger "wire," which is wound around a core of metal or fiber material. The construction of the cable provides for both flexibility and strength.

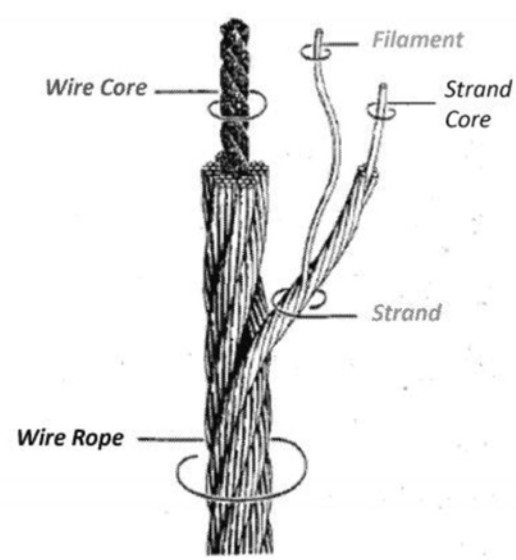


Figure 1: Typical wire rope assembly [2]

Intuitive-00029274

[41] Intuitive-00029274.
[42] *Id.*

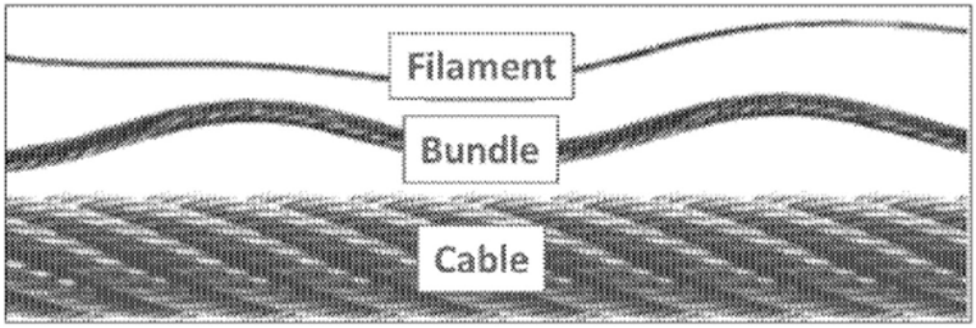
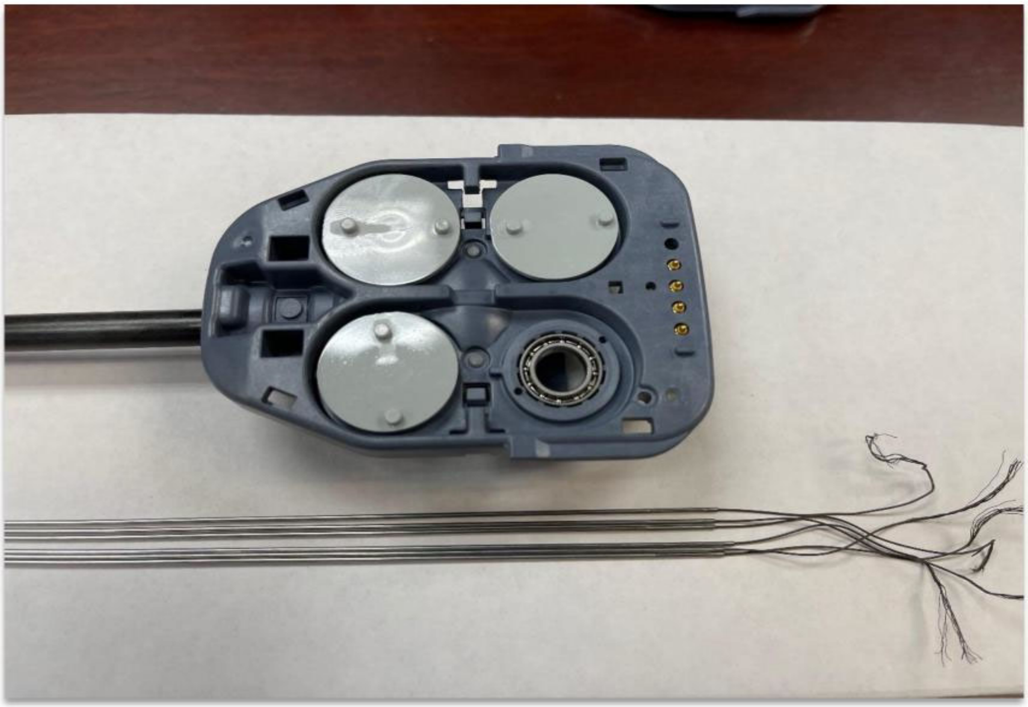


Figure 1 Overview of Tungsten Cable Construction

Another image of the cable construction is pictured in Intuitive's "Risk Benefit Analysis" document for tungsten drive cables. Intuitive-00536538

58. The Intuitive Si EndoWrist designs include cables crimped onto rods at both the proximal and distal ends. The cables freely move at the proximal and distal end around the pulleys, but do not move within the rods. The central rods are inside the full length of the shaft and transmit input motion from the proximal drive to the distal tool.



The cables and the rods onto which those cables are crimped appear on the bottom part of this image (illustration only). Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

59. The Xi design is similar, with the primary difference being cable routing at the proximal end of the instrument due to a 90-degree change in direction between the Xi input discs and shaft compared to the Si EndoWrist.[43]

60. The pulleys and exposed cable at the proximal and distal ends of the instrument are the locations at which the cables could potentially experience wear or damage. During the Rebotix inspection process, the cables are carefully examined at both ends of the EndoWrist (the proximal and the distal end) under a microscope with at least 10x magnification. This process pays particular attention to the areas of cable/pulley contact and interaction. If any fraying or breakage is detected

[43] Duque 30(b)(1) depo. tr., 48:23-52:20; Duque Ex. 241 at Intuitive-00027299.

on even a single wire of the cable, the instrument is not considered a candidate for repair and will not be serviced.[44]

61. This process of careful inspection comports with guidance provided by Intuitive to avoid issues with the cable drive system. For example:[45]

- 2-6: Before use, all instruments should be inspected for damage or irregularities.

62. Finally, the Rebotix process addresses any slack experienced by a cable that would cause unintuitive motion. The Rebotix process evaluates whether the EndoWrist instrument's cable drive system has developed any slack that would impede the proper functioning of the instrument. And each cable is tensioned in the instrument to remove any slack and restore proper tension.

63. Dr. Howe contends that "[c]ables tensioning protocols require test fixtures, torque measurement instruments, and accurate execution of a multi-step protocol" and that this is a "complicated process[.]"[46] The document Dr. Howe cites for this "complicated process" provides a simple two-page procedure,[47] and Intuitive's manufacturing engineers describe a simple manual or automated process for applying torque to tension the cables.[48] The Rebotix process for tensioning cables is consistent with, and indeed at least as robust as, the processes described by Intuitive documents and engineers.

64. In addition, Intuitive itself concluded that any instrument failures caused by cable failures do not pose risks to patients. When Intuitive analyzed the potential risks associated with

[44] Greg Fiegel Conversation.
[45] Intuitive-00536543.
[46] Howe Hospital Report ¶ 47.
[47] *See* Intuitive-00705141 (Intuitive Manufacturing Process Instructions (MPI) Cable Tensioning, 838012).
[48] Duque 30(b)(1) depo. tr., 136:24-146:13.

unintuitive motion that a cable failure could cause, in a document titled "Risk Benefit Analysis: Frayed and Broken Tungsten Drive Cables, Pitch and Grip," it concluded:[49]

> In any type of surgical procedure, an instrument that loses wristed motion as observed by the surgeon, whether upon insertion or later in the operation, will be immediately replaced with a properly functioning instrument. The immediate and long-range health effects of the use of such an affected instrument would be negligible.

65. Further, Intuitive concluded that cable fragments falling into the patient, even in a critical intra-cardiac operation, "would be easily retrieved and instrument replaced with only a brief delay in procedure."[50]

66. Intuitive summarized its conclusions about the ease of remedying potential cable-related issues during the medical procedure:[51]

> The user manual provides guidance on the handling of instruments to prevent damage to the cables. However, if damage does occur and fragments or filaments are generated, the visible material can be removed through piece-wise removal or by suction and irrigation. If fragments, filaments, or particulate are not retrieved, the materials meet recognized standards for long term and short term biocompatibility. If the cable damage does not generate fragments, filaments, or particulate in the patient, the instrument can quickly be replaced with a backup instrument, as instructed in the user manual.

67. And ultimately, when assessing the impact of cable fraying or breakage on patients, Intuitive concluded:[52]

> For both grip and pitch cables, the probability of adverse health effects is near zero.

68. Intuitive's conclusions are consistent with surgeons' experiences – these types of failures are easily identified and remedied should they occur during surgeries.[53]

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[49] Intuitive-00536541.
[50] Intuitive-00536542.
[51] Intuitive-00536544.
[52] Intuitive-00536543.
[53] Mahal Report ¶¶ 57-61; Rubach Report ¶¶ 11, 26-27; Estape depo. tr., 69:1-73:19.

69. Other Intuitive documentation confirms that such cable-related issues are either not a safety issue or "have additional mitigations to limit patient/user risk[.]" "Non-safety related features" are subject to 85%/85% reliability and confidence testing, while safety-related requirements "that have additional mitigations to limit patient/user risk" are subject to 90%/90% reliability and confidence testing.[54] Cable-related failures that Intuitive considers to be "non-safety related" include: "Instrument cables . . . derail from pulleys," "Instrument . . . fail[s] in a way that leaves jaws grasping tissue," out-of-spec pitch range of motion, out-of-spec grip range of motion, out-of-spec yaw range of motion, and out-of-spec instrument friction for roll, pitch, yaw, and grip.[55] Cable-related failures that "have additional mitigation to limit patient/user risk" include: "Instrument cables . . . partially or completely break," "Parts or pieces . . . detach from instrument that could fall into patient," and "Instrument [loses] intuitive motion performance during use."[56]

4. Rebotix's repair process addresses any instrument degradation from reprocessing.

70. Although Dr. Howe discusses reprocessing and sterilization generally, he does not cite to any evidence that the minimal number of reprocessing cycles experienced by EndoWrists impact cable drive life or performance in any manner, let alone any manner that would not be discovered or remedied through the Rebotix procedure. Rather, he cites to the U.S. Navy Wire-Rope Handbook for the general proposition that "[c]orrosion accelerates wire-rope deterioration"[57] and also asserts that Intuitive internal documentation states that "[w]hen the number of reprocessing cycles far outnumber the number of uses, early failures can occur."[58]

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[54] Duque Ex. 268 at Intuitive -02067026; Duque 30(b)(6) depo. tr., 46:5-47:2, 48:9-15, 50:22-51:25.
[55] Duque Ex. 268 at Intuitive -02067029-32 and Intuitive -02067034-37.
[56] Duque Ex. 268 at Intuitive -02067029-32 and Intuitive -02067034-37.
[57] Howe Hospital Report ¶ 42 & n. 35.
[58] *Id.* ¶ 41 & n. 34.

71. Dr. Howe also cites generally to the "White Paper, Extended Lives Supporting Materials" (Intuitive-00004692) at 4699-700 for the proposition that "[t]he need for these [life testing] precautions is clear from the observed life test failures and RMA returned instrument failures."[59] However, this document provides no data to support the proposition that corrosion due to reprocessing is a significant cause of failure of EndoWrists. Rather, it states that instruments, "when excessively reprocessed, . . . can fail before they reach their indicated number of uses," without ever defining what would constitute "excessive" reprocessing or discussing any actual failures due to excessive reprocessing.[60] The White Paper notes that FDA guidance requires data to validate reprocessing instructions, and acknowledges that it does not have hard data to back up the conclusion that reprocessing impacts instrument lives: "[I]t is *possible* that the implementation of the updated reprocessing guidance has reduced instrument damage during reprocessing . . . ."[61]

72. Without directly tying it to any specific failures, Intuitive contends that reprocessing can slowly relax the cables in the instrument.[62] For example, Intuitive testing indicates that, for untreated tungsten cables, reprocessing can result in up to a 0.6 µm (or approximately 2.4%) reduction in cable diameter after 200 minutes of exposure to an alkaline solution, while electropolished wire will have a 0.11 µm (or approximately 0.4%) reduction in cable diameter and gold-plated wire will have a 0.04 µm (or approximately 0.15%) reduction in cable diameter under such conditions.[63]

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[59] *Id.* ¶ 44.
[60] Intuitive-00004692 at 00004699.
[61] Intuitive-00004692 at 00004670.
[62] McGrogan depo. (*Rebotix*) tr., 54:15-25.
[63] Intuitive-00029273 at 00029297.

73. While Intuitive certainly has the ability to tighten cables,[64] it has never attempted to repair loose cables on an EndoWrist.[65]

74. Dr. Howe claims that corrosion results from reprocessing.[66] But Dr. Howe cites no document or other source that indicates that reprocessing leads to significant corrosion of the EndoWrist wire drive. Instead, he cites a Navy Wire-Rope Handbook that indicates that corrosion can be harmful to wire-ropes.[67] Moist, marine environments create rapid-pitting corrosion, which is not representative of the environment EndoWrists are used in.[68] Dr. Howe never provides any detail about the amount of corrosion that would be harmful to an EndoWrist cable system, or even how a properly performed reprocessing cycle introduces corrosion.

75. And Dr. Howe's own cited handbook confirms that corrosion can be counteracted by "using a corrosion-resistant wire material such as stainless steel."[69] Intuitive's cable wires are composed of corrosion-resistant material: the rods are made of stainless steel, and tungsten cables are corrosion resistant.[70] Intuitive's own cable supplier confirms that the Tungsten cables that it manufactures for Intuitive have "strong corrosion resistance."[71] Further, Intuitive uses a stainless-steel alloy (303 SS) for the rods in its cable construction.[72] 303 SS has "good corrosion resistance."[73]

[64] McGrogan depo. (*Rebotix*) tr., 55:9-18.
[65] DeSantis depo. (*Rebotix*) tr., 272:15-23; McGrogan depo. (*Rebotix*) tr., 55:20-24.
[66] Howe Hospital Report ¶ 42.
[67] *Id.* ¶ 42, fn. 35.
[68] "303 Stainless Steel." Penn Stainless, 5 Dec. 2018, https://www.pennstainless.com/resources/product-information/stainless-grades/300-series/303-stainless-steel/
[69] Navy Wire-Rope Handbook Vol 1. Page 3-16.
[70] https://www.savacable.com/blog/tungsten-wire-the-perfect-fit-for-surgical-robots; https://www.savacable.com/blog/the-benefits-of-tungsten-cable
[71] "Tungsten." *Elmet Technologies*, www.elmettechnologies.com/tungsten/.
[72] Intuitive-00521056.
[73] Steel, Alro. "303 Stainless Steel." *303 Stainless Steel | Chromium-Nickel Stainless Steel | Alro Steel*, www.alro.com/divsteel/metals_gridpt.aspx?gp=0117.

76. Moreover, Rebotix's service process addresses any impactful corrosion. Rebotix extensively examines the proximal housing, its components, and the cable drive system for any sign of corrosion or degradation.[74] If any corrosion is detected, the instrument is not serviced. Moreover, the ultrasonic cleaning that the instrument is subjected to before being sent back to hospitals removes any corrosion, rust, or debris.[75]

VI. THE REBOTIX REPAIR PROCESS IS MUCH MORE THAN A "RESET" AND ADEQUATELY ADDRESSES THE EFFECTS OF WEAR AND TEAR THAT ACCRUE DURING ENDOWRIST USAGE.

77. In my report below, I discuss the Rebotix repair process that I personally observed at the Rebotix facility. I further discuss the Rebotix repair process and some of the supporting documentation in more detail. I understand that EndoWrist repairs performed for SIS customers, prior to Intuitive shutting down SIS's EndoWrist repair business, were performed by Rebotix.[76]

78. I understand that (a) SIS was in negotiations with Rebotix to perform that repair process itself at SIS facilities,[77] and (b) in connection with those negotiations, Rebotix did a test run of that process at SIS's facility for a major EndoWrist repair customer, Banner Health.[78]

A. My experience with the Rebotix service procedure confirmed that the instruments serviced by Rebotix operate in the same manner as new EndoWrist instruments sold by Intuitive

79. As part of my engagement in this matter, I inspected the Rebotix repair facility in St. Petersburg, Florida. I was able to observe several complete EndoWrist repair processes, compare EndoWrists repaired by Rebotix to brand new EndoWrists sold by Intuitive, and examine

[74] Fiegel Conversation, REBOTIX082680.
[75] REBOTIX077469
[76] K. Johnson 30(b)(6) depo. tr., 19:5-20:1, 33:22-34-11.
[77] K. Johnson 30(b)(6) depo. tr., 33:9-18; Posdal 30(b)(1) depo. tr., 28:13-29:24.
[78] Posdal 30(b)(1) depo. tr., 30:5-15.

a number of EndoWrists that Rebotix received from hospital customers that Rebotix had determined were not suitable candidates for repair. I interviewed Greg Fiegel, the Rebotix Director of Operations in charge of all Rebotix repair services for EndoWrists. I personally reviewed each step of the Rebotix repair process, including the entire process from receipt of the EndoWrist devices from the customer, inspection, repair, and outgoing inspection before the devices are returned to the customer.

80. I was also able to examine the types of failure modes that EndoWrists experience. I encountered unintuitive motion, misaligned graspers, stretched cables, and fully broken cables, among other failure modes.

B. <u>Incoming Inspection and Screening</u>

81. When an EndoWrist is received from a customer to be repaired, Rebotix logs that EndoWrist in its inventory. Rebotix then scrubs, flushes, disinfects, and sterilizes that device, as shown in the *EndoWrist Instruments Reprocessing Wall Chart* below.

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

82. After this initial process of ultrasonic cleaning and sterilization, Rebotix performs an initial inspection of the device. As part of that inspection, Rebotix removes the housing at the proximal end of the EndoWrist. A Rebotix technician then performs an initial visual inspection of

the entire device to scan for any indication of damage. Rebotix also checks the use counter to determine the number of uses remaining on the device.

This photo shows a selection of the EndoWrists that Rebotix received. The housing on each EndoWrist is removed. The bottom EndoWrist has had the cable system detached for illustration and examination (this is not a standard repair step). Rebotix's Interceptor assembly appears at the top of the image. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

83. After the initial visual check, a Rebotix technician uses an optical microscope at high magnification to examine the tool end of the EndoWrist (the scissors, graspers, etc.), the exposed cables, and the pulley system at both the proximal and distal ends of the device. During this step, Rebotix looks for signs of cable fraying, cables misaligned with pulleys, pulley damage,

damage to the main tube of the instrument, and any corrosion or contamination on the instrument bearings or the cables.

84. In addition to the visual inspection, when assessing whether the instrument is a candidate for repair, Rebotix operates each drive component through its full range of motion. During this process, Rebotix may determine that a cable has slipped off a pulley and become misaligned or that the device is otherwise unable to operate in its full range of motion.

85. For electrosurgical instruments, Rebotix performs the "Hipot Test" test sequence to ensure that the instruments' insulation and electrical isolation is functioning as required. The test sequence indicates whether there is any damage or breakdown in the electrical insulation and isolation of the device, or another issue that prevents the electrosurgical components from functioning safely in terms of their electrical behavior.

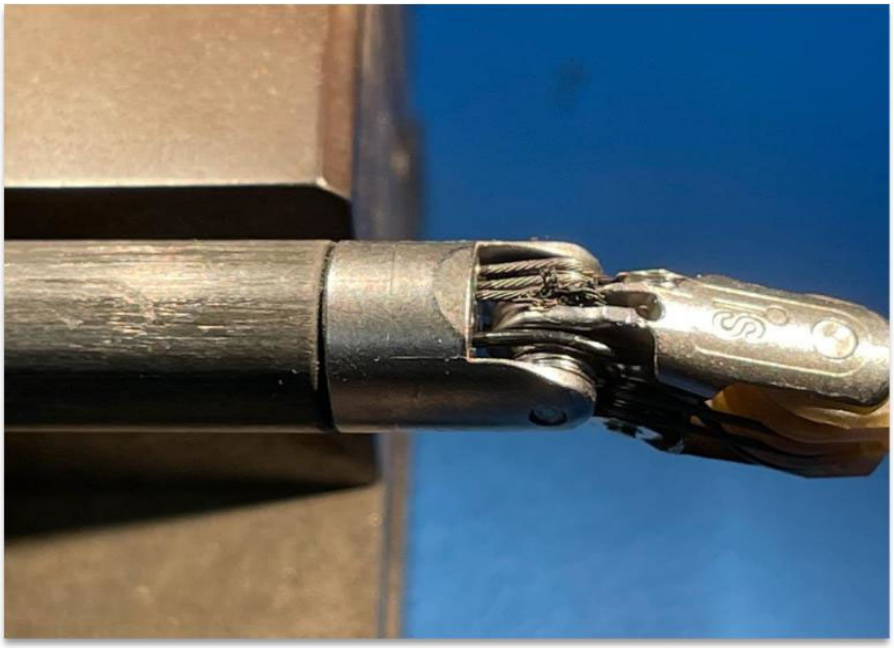
This is a photo I took of the Dielectric Withstand Tester that Rebotix uses to run the "Hipot Test" to verify the insulation of electrosurgical EndoWrists. The programmed test sequence results in either a Pass or a Fail result. If the test reads "Fail" instead of "Pass," the instrument is not a candidate for repair. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

86. These initial inspections are meant to identify whether there is any existing damage to the EndoWrist device that indicates that it is "Unsuitable for Repair." Instruments can be "Unsuitable for Repair" due to frayed or broken cables, damage to the pulley system (including sheared pins or broken bearings), or due to broken instrument tips. Similarly, if there is any damage to an electrosurgical instrument's insulation or the instrument fails the electrosurgical insulation/isolation test, the instrument will not be a candidate for repair.

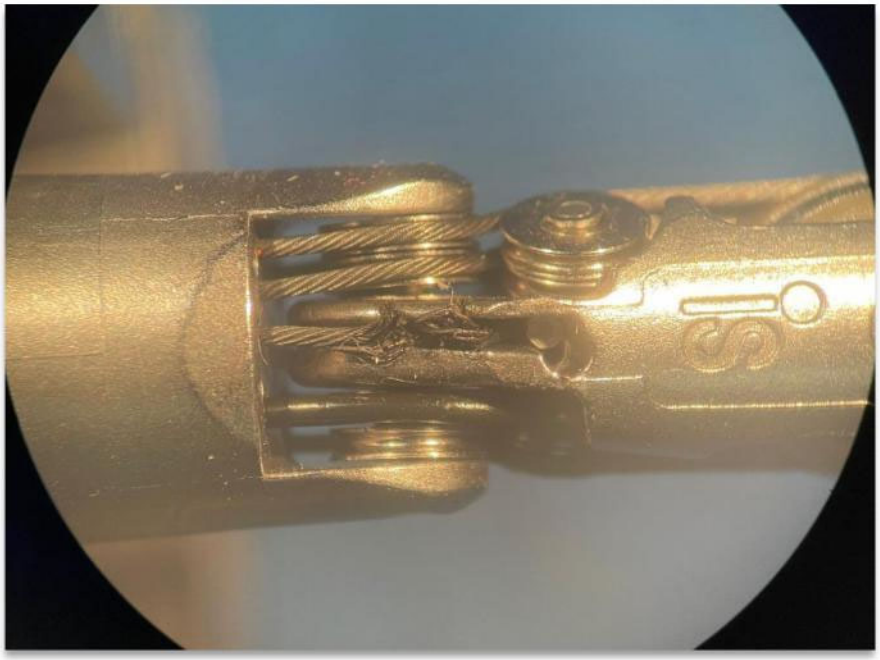
87. When Rebotix determines that an instrument is "Unsuitable for Repair," Rebotix then notifies the hospital that submitted that EndoWrist of that determination. At that point, the device may be returned to the customer or remain in inventory at Rebotix and be labeled as "non-repairable."

88. I inspected several devices at Rebotix that were deemed to be "Unsuitable for Repair." As an example, an EndoWrist with a severed cable was not a repair candidate.

This picture is of an EndoWrist that Rebotix received from a hospital customer that was deemed "Unsuitable for Repair" due to cable damage. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.



This is a photo I took of the same EndoWrist. The frayed cable is clearly visible at the distal end of the EndoWrist. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

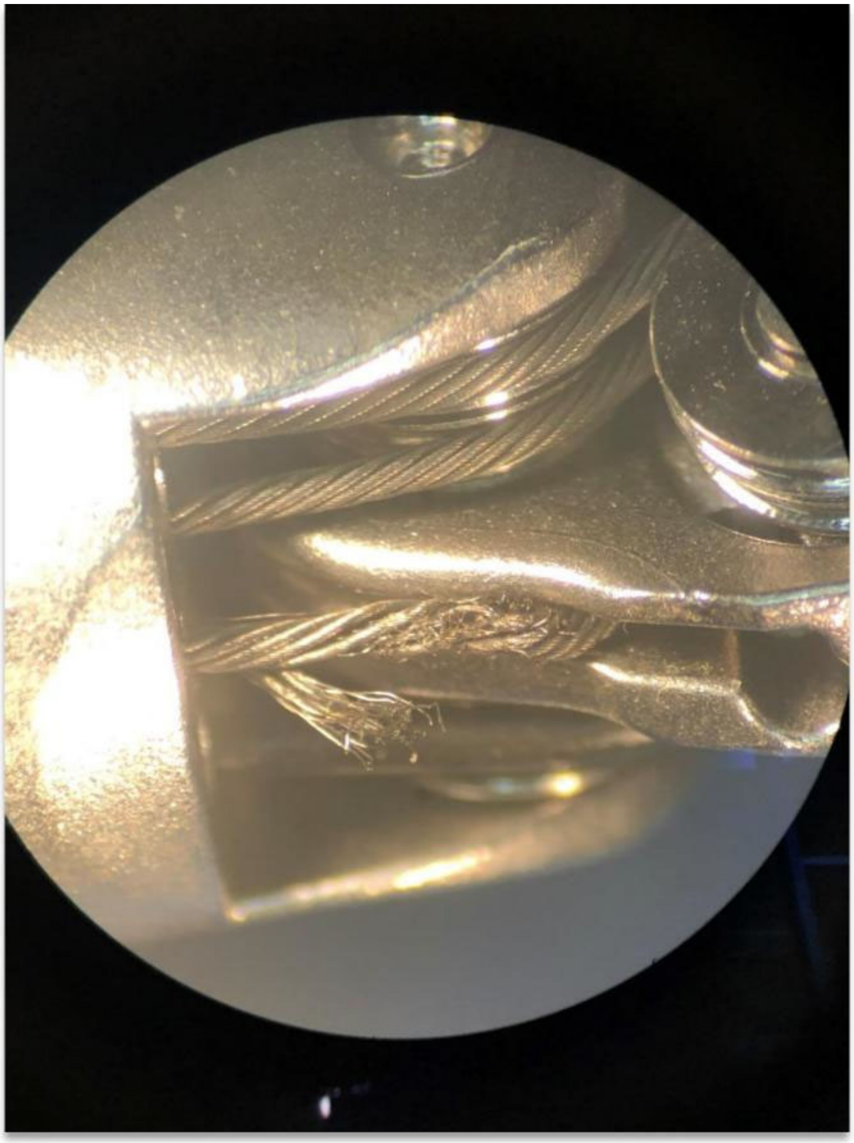


This is a picture of the same EndoWrist under an optical microscope. The cable tear is clearly visible. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

89. This EndoWrist still had remaining uses on the use counter, indicating that the failure had occurred before the instrument had reached its maximum number of uses. This instrument was received by Rebotix from a hospital that had performed a visual inspection prior to surgery.

90. As another example, a PK dissecting forceps with four remaining uses was found to be unsuitable for repair due to a cable break.

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.



Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

91. In my examination of the EndoWrists that were "Unsuitable for Repair," I did not detect damage due to wear on the instrument. For example, in the cables above, one of the cables in each instrument experienced a break, while the others were fully intact with no signs of fraying. The discrepancy between the cables (one displaying significant damage and the others showing no sign of wear) indicates that one cable was subject to damage from an external object or from

misuse. Other instruments with cables that I examined similarly reflected external damage and breakage, rather than normal wear.

92. This incoming inspection and screening is critical in order to identify EndoWrists with damage that are "Unsuitable for Repair."

C. Interceptor Installation for Use Counter Reset

93. Once an instrument has been identified as a candidate for repair, Rebotix performs a use counter reset by installing the Interceptor component. By doing so, Rebotix restores the use counter to its original value. In other words, if the use counter for an EndoWrist instrument is initially set to ten uses, Rebotix will reset the use counter to the same value of ten uses. By setting the counter back to the same value as the original, Rebotix ensures that the EndoWrists will be sent in for inspection and repair after that limited number of uses. By contrast, traditional laparoscopic instruments do not have a use counter and therefore, are sent in for inspection and repair only when necessary, but not at regular intervals.

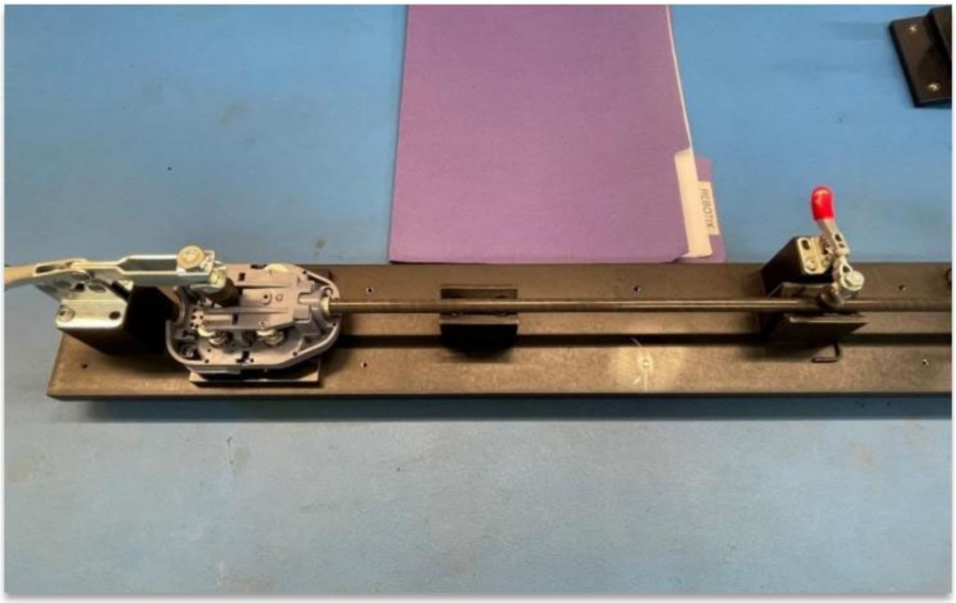
D. Adjustment and Repair

94. After the Interceptor is installed, Rebotix then performs any needed repairs on the tool end of the EndoWrists, such as sharpening scissors, aligning graspers, or ensuring sufficient tightness on needle drivers. Rebotix then makes any needed adjustments to the cables. Rebotix places the EndoWrist in a special fixture and locks the device in its neutral position. This tensioning process involves (a) adjustment of the cable tension, and (b) testing the EndoWrist range of motion and no-load torque for each drive wheel to ensure that the tension is appropriate for surgical use. I personally tensioned the cables on an EndoWrist and was able to readily identify over-tensioning or under-tensioning of the cable. An under-tensioned cable fails to communicate

movements precisely to the distal end, while an over-tensioned cable requires excessive additional torque on the drive wheels at the EndoWrist proximal housing to operate. Indeed, this process is similar to the process utilized by Intuitive for cable tensioning of its Si EndoWrists, while for Xi EndoWrists a similar process is performed using an automated fixture.[79]

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

[79] Duque 30(b)(1) depo. tr., 136:24-146:13.



The Rebotix designed fixture for cable adjustment and tensioning holds the EndoWrist steady in its neutral position and allows for cable tension to be calibrated. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

E. <u>Outgoing Inspection and Evaluation</u>

95. Finally, Rebotix conducts a series of tests on the instrument as part of an outgoing evaluation.[80] As part of that process, Rebotix verifies that the use counter reset was successful and that the instrument shows the original specified number of uses. Rebotix also evaluates whether the instrument's motion is functioning as expected, and whether the tool end of the instrument is performing appropriately (for example, cutting tissue or grasping). In addition, Rebotix performs a second round of testing for electrosurgical EndoWrists in order to verify the integrity of the electrical insulation and isolation of the device.

[80] REBOTIX123448; REBOTIX134750-REBOTIX134754; REBOTIX134655-134656.

96. If the EndoWrist passes all of the testing and inspection processes and is deemed fully functional, it is then subjected to another full cleaning process, which includes scrubbing, flushing, disinfection, and sterilization. Although EndoWrists are not shipped back to hospitals as sterile, and thus need to be reprocessed upon receipt, this cleaning process ensures that any debris or particulate matter is removed from the EndoWrist.

97. The EndoWrist is then repackaged and returned to the customer. Only an EndoWrist that satisfies both the Rebotix initial quality inspection and the Rebotix final inspection protocol will be returned to the hospital that originally sent that EndoWrist to Rebotix for repair.

F. Repair Process Returns EndoWrists to Original Functional Specifications

98. When Rebotix repairs an EndoWrist instrument, it performs a series of steps that are designed to return the EndoWrist to its original functioning specifications. As part of that process, it sharpens scissors, tightens loose cables, and ensures that the instrument performs in a manner equivalent to a new instrument.

99. Rebotix then installs the Interceptor chip, which resets the use counter to its original specification.[81] Rebotix does not increase the use counter to a value beyond the initially specified number of uses. And Rebotix does not otherwise alter the function of the instrument in any way.

100. The equivalent performance between EndoWrists repaired by Rebotix and those sold new by Intuitive has been confirmed by hospitals that have used the Rebotix repair service.

101. When Pullman Regional tested Rebotix-repaired instruments, they determined that "[t]here was no difference than the non-reprocessed instruments," and "didn't have any issues"

[81] *See, e.g.,* REBOTIX162185.

with the Rebotix-repaired instruments.[82] None of the members of the surgery team at Pullman were able to identify any difference between the Rebotix-repaired EndoWrists and EndoWrists that had not been repaired or serviced by Rebotix.[83] In follow up interviews with the surgical teams that used Rebotix-repaired EndoWrists, Pullman learned "[t]hat the instruments still worked just like the nonrepaired ones. There was no difference."[84]

VII. RESTORE AND SIS PROPERLY RELIED ON THE EXPERTISE OF THEIR TRUSTED TECHNOLOGY PARTNER, REBOTIX

102. Dr. Howe faults Restore and SIS because they "did no independent testing of the EndoWrist instrument reset [sic, repair] process and instead relied on Rebotix's testing."[85] As discussed below, Restore and SIS properly relied on the testing of their trusted technology partner, Rebotix, regarding the EndoWrist repair process.

103. Dr. Howe faults Restore for relying on the "DQS MED Technical File Review."[86] However, Dr. Howe acknowledges that this material includes a "brief summary" that Rebotix's "simulated use life-testing protocol verified certain requirements during and after a total of 10 additional uses."[87] Dr. Howe similarly faults SIS for relying on the "Summary of Quality and Reliability Measures" document.[88] But as Dr. Howe admits,[89] that document provides a "listing of the processes, standards, and tests," including that "A detailed FMEA (Failure Modes and Effects Analysis) was performed covering the service process."[90] Dr. Howe further acknowledges that this

[82] Harrich depo. (*Rebotix*) tr., 37:1 – 38:1.
[83] *Id*. at 38:9 – 39:3.
[84] *Id*. at 40:2-8.
[85] Howe Hospital Report ¶ 130; *see also id.* ¶ 128.
[86] Howe Hospital Report ¶ 129.
[87] *Id.*; *see also* K. May Deposition Exhibit 1 (REBOTIX005310- REBOTIX005333).
[88] Howe Hospital Report ¶ 130.
[89] *Id.* ¶ 131.
[90] Def.'s Ex. 136, SIS095115-095139.

document also explained that (a) Rebotix performed "formal life testing to establish reliability,"[91] (b) Rebotix performed "A worst-case analysis . . . to determine which models should be used during performance and life testing,"[92] (c) "a smaller batch of representative models were subjected to over 50 cleaning and sterilization cycles to demonstrate the robust nature of the instrument's design,"[93] and (d) "over two dozen industry standards" were "considered and applied to the development process."[94]

104. Not only were Restore and SIS entirely reasonable in relying on these representations, but Rebotix's representations were truthful and its testing and procedures extremely robust, as discussed below.

A. <u>Reverse Engineering to Develop Specifications</u>

105. In my experience, reverse engineering the original specifications of an instrument is a common practice used by mechanical engineers in understanding instruments and their functions. Original specifications for instruments are often not published, and repair companies seeking to return an instrument to its original specifications need to conduct a thorough reverse engineering process. Reverse engineering typically involves two steps: (1) testing a new instrument to understand and establish its specifications, and then (2) testing a repaired or serviced instrument to ensure that it functions in the same manner as a new instrument. Rebotix performed these steps in its initial testing.

106. Before servicing EndoWrists, Rebotix extensively tested new EndoWrists to establish the baseline specifications for EndoWrists. As part of that complete evaluation, Rebotix

[91] Howe Hospital Report ¶ 132.
[92] *Id.* ¶ 134.
[93] *Id.* ¶ 135.
[94] *Id.* ¶ 136.

assessed cable tension, wheel torque values, scissor sharpness, grasper alignment, insulation strength, and motion handling by the instrument.[95] This process represented a significant effort by Rebotix and was completed over the course of twelve to eighteen months.[96]

107. Rebotix documented the test results in a series of specification documents.[97] Those documents are used during Rebotix's repair process to ensure that the instruments comport with Intuitive's specifications.

108. After Rebotix documented the original specifications and developed its repair process, it employed third-party testing laboratories to verify that its repaired EndoWrists complied with all applicable safety standards. Rebotix sent its repaired EndoWrists to SGS for electrical safety testing,[98] and IMR Test labs for materials testing.[99] Rebotix then had its entire service process evaluated by DQS-Med to confirm that it complied with all applicable safety standards.[100]

109. The result of this robust initial reverse engineering process and subsequent testing is a repair process that safely and effectively ensures that repaired EndoWrists can continue to be used by hospital customers.

B. <u>Risk Management</u>

1. <u>Risk management related to wear and tear</u>

110. Dr. Howe contends that the Rebotix repair process does not "adequately address the effects of wear and tear that accrue during instrument usage."[101] His opinion is wrong and

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[95] Greg Fiegel conversation, *see also* REBOTIX075431-075433, REBOTIX075420, REBOTIX089137.
[96] Greg Fiegel conversation.
[97] REBOTIX133235- REBOTIX133311, REBOTIX133337- REBOTIX133353, REBOTIX133373.
[98] REBOTIX128851.
[99] REBOTIX092208.
[100] REBOTIX083098.
[101] Howe Hospital Report ¶ 19.

misleading in at least two respects. First, as I discuss in detail below, Intuitive's use counter itself in no way "adequately addresses the wear and tear that accrue during instrument usage."

111. Second, Rebotix does consider "wear and tear" suffered by instruments beyond the original number of uses.

112. In fact, Rebotix explicitly considers "tear" in its initial inspection of the instrument. Based on that inspection, any "tear" or breakage suffered by an instrument prior to Rebotix receiving it renders it ineligible for repair. For example, EndoWrist instruments with broken scissors, snapped graspers, or frayed cables will not be repaired by Rebotix.

113. As I discussed in detail, Rebotix's repair process also accounts for any wear that the instrument has experienced. For example, it accounts for the dulling of scissors or the misalignment of graspers, as well as any loss of tension in cables through the cable tensioning process and drive wheel torque evaluation. Rebotix's life testing confirms that the instrument continues to operate just as a new EndoWrist would through its additional lives.

114. Rebotix seriously considered all potential failure modes of EndoWrists in its design plan and testing. In its risk management documents, Rebotix concluded that any increase in "any estimated hazard severity or probability of occurrence" would need to be investigated and mitigated.[102] To that end, Rebotix conducted extensive life testing to ensure that its repaired EndoWrist instruments continued to operate and function in the same manner as new Intuitive EndoWrists. Rebotix's life testing confirmed that its repairs resulted in no increase in hazard severity or probability of occurrence.

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[102] REBOTIX123794.

2. Consideration of Mechanical Forces

115. Dr. Howe claims that Rebotix's risk management protocols simply assume that Rebotix can restore the instrument to the same function as a new EndoWrist, and that it does not consider any risks from continued use significant.[103] But Rebotix's development of its repair process and its extensive testing of instruments beyond the original lives on the use counter refute this point.

116. Rebotix seriously considered all potential failure modes of EndoWrists in its design plan and testing. In its risk management documents, Rebotix concluded that any increase in "any estimated hazard severity or probability of occurrence" would need to be investigated and mitigated.[104] To that end, Rebotix conducted extensive life testing to ensure that its repaired EndoWrist instruments continued to operate and function in the same manner as new Intuitive EndoWrists. Rebotix's life testing confirmed that its repairs resulted in no increase in hazard severity or probability of occurrence.

117. Dr. Howe further claims that Rebotix's failure to consider mechanical forces is demonstrated by its failure to mention those forces in its "Interceptor Circuit Card Risk Analysis and Assessment."[105] Just as the EndoWrist design does not place any mechanical load on the original circuit board, so too there is no load placed on the Interceptor assembly that replaces the circuit board. A conclusion that the Interceptor is not exposed to mechanical forces does not mean that Rebotix does not consider the role of those forces in its service process.

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[103] Howe Hospital Report ¶¶ 21, 98.

[104] REBOTIX123794.

[105] Howe Hospital Report ¶ 105. The "Interceptor Circuit Card Risk Analysis and Assessment" only deals with any additional risk from installation of the Interceptor, and concludes that mechanical forces do not act on that Interceptor assembly. *See also* REBOTIX084679.

3. MDR Report with Mechanical Forces

118. Dr. Howe analyzes an MDR report and concludes that it shows that mechanical failures increased with the number of uses.[106] Dr. Howe asserts that the MDR report demonstrates that instruments wear over time.[107] And Dr. Howe claims that Rebotix ignored this data and "ignored the damage that occurs in normal surgical use of these instruments."[108] I disagree with Dr. Howe on this issue.

119. Dr. Howe's conclusions based on this document are flawed. Several different aspects of the flaws in Dr. Howe's assertions are discussed below.

120. First, the report only deals with a subset of reported returns. Intuitive receives, according to witness testimony, tens of thousands of RMA instruments per year.[109] The sampling of instruments in the report is not sufficiently broad to draw overall conclusions about instrument failures.

121. Second, Dr. Howe fails to discuss several other important conclusions contained in the report. About half of the returned EndoWrists in the report were misused, as opposed to being simply subject to normal surgical use. Intuitive frequently attributes misuse or damage during reprocessing as the cause of specific failures.

> "After data examination, about half of the returned Endowrists could be considered misused. Misuse was defined as any action contrary to the directions for use (DFU) such as using an endowrist to clean another endowrist, overloading at the tip, tensile loading, excessive force on the grip, tip, or clevis, improper cleaning procedures, and improper set up the monopolar and bipolar cords."[110]

[106] Howe Hospital Report ¶¶ 109-110.
[107] *Id.* ¶ 113.
[108] *Id.* ¶ 114.
[109] DeSantis depo. (*Rebotix*) tr., 202:7-22.
[110] REBOTIX090160.

122. The failure of misused instruments does not indicate that those instruments become more likely to fail over time. Misuse or external damage during cleaning and handling steps may occur at any time during the life of an EndoWrist.

123. Third, the report includes instruments that were subject to recalls for defective parts. For example, monopolar curve scissors had a recall that dealt with design flaws that were causing failures.[111] As another example, the FDA issued a recall of large needle drivers.[112] These recalls are factors that show that the report is not representative of actual usage for instruments without defective parts.

124. Fourth, the report's discussion of instruments returned with remaining uses is not representative of typical failures for EndoWrists. For example, the MDR report page cited by Dr. Howe gives a sample of 61 instruments returned with lives remaining.[113] This is an incredibly small sample that does not take into account the remaining uses on the other instruments involved in the MDR report (well over 1000).

125. Fifth, the conclusions that Dr. Howe draws from the unrepresentative sample of instruments referenced in the MDR report are flawed.

126. Dr. Howe claims that this table with 61 instruments shows that instruments wear out and show increased failure rates with increased usage. But the number of instruments that were returned with 0 uses remaining (11) was the same as the number of instruments returned with 7,

[111] REBOTIX090161-REBOTIX090162.
[112] REBOTIX090166.
[113] REBOTIX090164.

8, and 9 uses remaining (11). And more instruments were returned with five uses remaining than were returned with one use remaining.

127. Sixth, Dr. Howe ignores statements in the underlying MAUDE sub report about the inability to draw conclusions about usage data because it is so often not recorded.

> "In reviewing the bipolar class of instruments, there does not appear to have enough information in the database to show an increase of burns as the instrument is used. Lives remaining information was not captured in most of the records."[114]

128. The report provided the same conclusion for monopolar cautery instruments.[115]

129. Moreover, Dr. Howe's claim that Rebotix "ignores" damage that occurs to instruments is inaccurate. Dr. Howe does not account for the initial evaluation of instruments that Rebotix conducts. The Rebotix repair process begins with a thorough evaluation of the instrument that determines whether any issue exists that would make the instrument unsuitable for repair. This initial inspection is a critical and essential part of the Rebotix repair process. Rebotix would not service any instrument that suffered cable breaks due to misuse or wear and tear prior to their useful life expiring.

C. <u>Life Testing</u>

130. Dr. Howe also criticizes the Rebotix life testing.[116] However, as discussed below, the Rebotix life testing procedure is robust and fully supports the safety and efficacy of EndoWrists repaired by the Rebotix repair process.

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[114] REBOTIX089912.
[115] REBOTIX089913.
[116] Howe Hospital Report ¶¶ 115-126.

131. Rebotix specifically performs numerous tests to expose instruments to excessive mechanical forces.

132. For example, in Rebotix's life testing, the following mechanical safety instruction is included in each of the testing procedures:

> **mechanical safety rough handling**
>
> The Device shall withstand the stresses caused by rough handling as defined in IEC60601-1: 2005 15.3.1 Table 28 for Hand-Held device: Push 15.3.2, Drop 15.3.4.1, Molding stress relief 15.3.6. (Mold Stress Relief only)

REBOTIX132477

133. Rebotix further ensures that the instruments are subjected to the same mechanical strains they would face during surgery. During life testing, Rebotix ensured that instruments are tested in a manner that corresponds with surgical use. The graspers were tested for their ability to successfully grasp tissue,[117] scissors were tested to successfully cut tissue,[118] and the electrosurgical instruments were tested to successfully cauterize tissue.[119] And each instrument's range of movement was tested in every direction—pitch, yaw, and rotation.[120]

134. To determine how many times each instrument should be tested in this way for each use, Rebotix surveyed a number of surgeons to establish the "high end number of manipulations/activations for any given function of the EndoWrist surgical tool end."[121] From this survey, Rebotix established that this high-end number of manipulations/activations of a specific EndoWrist was 60 activations for each action (Pitch, Yaw, Grip, Roll).

[117] REBOTIX170283-REBOTIX170284.
[118] REBOTIX170075-REBOTIX170076.
[119] REBOTIX170077-REBOTIX170078.
[120] REBOTIX170075.
[121] REBOTIX170053.

135. Rebotix then performed each separate part of its testing 72 times. Each instrument was manipulated in each direction 72 times per use. It grasped, cut, or cauterized tissue 72 times per use (using chicken breast as simulated tissue). Because Rebotix performed 11 life tests, each tool was required to pass 792 (11x72) test interactions in each direction with the chicken breast.[122]

136. This testing reflects the mechanical wear that an instrument would experience during surgery, and tests even above the high-end number of instrument manipulations from the surgeon survey, to ensure that the instrument can be safely used.

137. Dr. Howe asserts that Rebotix's life testing with chicken breast is not adequate because there was no "significant force applied to the instruments."[123] Intuitive's life testing is on new EndoWrist instruments and does not take into account the possibility of repair. In fact, Intuitive has never conducted any life testing on an instrument after that instrument has been repaired.[124] In fact, Intuitive has never determined the likelihood of cable failures after re-tensioning. These differences mean that life testing by Intuitive and life testing by Rebotix cannot be directly compared.

1. <u>Statistical analysis for number of uses</u>

138. Rebotix performed its life testing using statistical analysis by using a specified number of samples to establish a particular level of reliability. Rebotix initially identified the worst-case instruments that were expected to experience the highest loads and that were most likely to fail testing. A worst-case model "means that no other [Endo]Wrists represent a greater risk of failure."[125] When selecting which EndoWrists would undergo testing, Rebotix evaluated

[122] *See, e.g.*, REBOTIX170075.
[123] Howe Hospital Report ¶ 119.
[124] Duque 30(b)(1) depo. tr., 149:9-151:8; DeSantis depo. (*Rebotix*) tr., 210:15-212:1.
[125] REBOTIX146771.

which of the EndoWrist tool ends in each category would suffer the highest stresses from surgery, and then selected representative models that would test each different tool type.[126] Intuitive also uses worst-case testing for its testing of EndoWrists.[127]

139. The Rebotix life testing protocols selected 22 samples of each of the identified worst-case EndoWrists for testing "to provide the level of statistical significance at 90% confidence of 90% reliability when no failures are observed."[128] None of the sample instruments that Rebotix tested produced a failure, satisfying the desired level of statistical confidence.[129]

2. Rebotix's life testing results

140. Dr. Howe asserts that a lack of failures in Rebotix testing compared to Intuitive testing "provides further evidence of the inadequacy of the Rebotix life test protocols to simulate surgical usage."[130] I disagree with this assertion.

141. Dr. Howe does not consider the possibility that EndoWrists repaired by Rebotix exhibited no failures in life testing, due to an effective and thorough repair process that results in a device that is comprehensively tested multiple times. Dr. Howe is comparing repaired EndoWrists to newly manufactured Intuitive devices that are not necessarily subjected to the same level of inspection, testing, and adjusting performed by Rebotix during its repair process. Dr. Howe is attempting to compare the testing for EndoWrist instruments repaired by Rebotix with new EndoWrists: "In Intuitive's Extended Use Program testing, twelve different X/Xi instrument models and a total of 250 instruments were tested."[131] As I said above, each device that Rebotix

[126] *Id*.
[127] Duque 30(b)(6) depo. tr., 66:12-68:7; Duque Ex. 269 (Intuitive-00290826).
[128] REBOTIX170058.
[129] REBOTIX170345.
[130] Howe Hospital Report ¶ 126.
[131] *Id.* ¶ 124.

receives from a hospital customer must meet an initial inspection to ensure that it is capable of being repaired. That device is then repaired, and then tested again to ensure that it is fully functional. Intuitive's Extended Use Program testing was the first time Intuitive actually tested any devices to failure, rather than just validating a prescribed number of lives, and even many of those devices were not tested to failure.[132] In the Extended Use Program, Intuitive showed that even without repair, EndoWrists could be used for 14 to 20 lives (without any repair steps), even when subjected to the Intuitive Surgical Use Cycle (SUC) prescribed in its testing procedure.[133] The testing programs and the condition of the devices under test are clearly different between Intuitive and Rebotix.

142. Dr. Howe's analysis is also flawed for three additional reasons.

143. First, Intuitive's life testing is on new EndoWrist instruments, and does not take into account the possibility of repair. Intuitive has never conducted any life testing on an instrument after that instrument has been repaired. For example, Intuitive has never determined the likelihood of cable failures after re-tensioning. These differences mean that life testing by Intuitive and life testing by Rebotix cannot be directly compared.

144. Second, much of Intuitive's life testing involves testing design changes or proposed alterations to a product that may not even be an EndoWrist that could be sold but rather an internal evaluation device, while Rebotix is merely validating the effectiveness and adequacy of repairs to EndoWrists that were previously sold to end user hospitals and medical centers. Two of the example documents cited by Dr. Howe involved testing instruments "[t]o evaluate the

[132] Intuitive-00552535.
[133] Intuitive-00552535.

proposed changes."[134] These design-stage tests are not comparable to Rebotix's testing of instruments that have already been used.

145. Third, Rebotix's life testing protocols adequately reflect the stresses that an instrument experiences during surgical use. The lack of failures during Rebotix's life testing protocols is indicative of the success of the repair process, not the inadequacy of the life testing process.

146. The "Tool End Design" types considered by Rebotix included the categories: "… Scissors, Graspers, Needle Drivers, and Non-opening Cautery (tool ends do not open and close). In addition, certain Wrists models deliver RF energy ("Energized Wrists"). Energized Wrists are either Monopolar, Bipolar, or PK."[135] The specific devices considered worst-case in the Rebotix life testing included:[136]

- 420179 Monopolar Curved Scissors
- 420184 Permanent Cautery Spatula
- 420205 Fenestrated Bipolar Forceps
- 420006 Large Needle Drive
- 420093 ProGrasp Forceps
- 420227 PK Dissecting Forceps

147. Dr. Howe focuses on Intuitive's use of a Weibull model, which he describes as "a well-recognized and appropriate method for modeling the reliability of instruments."[137] While I

[134] Intuitive-00546360, Intuitive-00544497.
[135] REBOTIX146772.
[136] REBOTIX146772.
[137] Howe Hospital Report ¶ 72.

do not disagree with this general statement, the output of a Weibull model is limited by the data that is used to create the model. Intuitive generally used Weibull models not to determine the maximum life of EndoWrist instruments, but to validate a target number of lives set by its marketing personnel.[138] Thus, Intuitive often intentionally limited the input data provided to the Weibull models,[139] which in turn results in less accurate projections beyond the marketing-selected number of lives. In contrast, actual RMA data shows essentially a near constant linear pattern for instrument failures (shown as number of RMAs), indicating that an instrument is no more likely to fail on any particular "life" or "use," just because it has been used a number of times previously.[140]

3. Rebotix's safety margin

148. Rebotix performed reprocessing cycles after each simulated surgical use cycle to model the stresses that the device would experience from reprocessing.[141] And, as discussed below, because Rebotix conducted two rounds of life testing, it exposed instruments to at least 20 additional reprocessing cycles. None of the instruments experienced failure over the course of those reprocessing cycles.[142]

149. The Rebotix life testing assumes the proper inspection and servicing of instruments every ten uses. One round of the Rebotix life testing involved instruments that had already been used for nine uses, then were repaired by Rebotix and subjected to a further life testing for eleven

[138] McGrogan depo. tr., 64:5-19, 65:19-25; Intuitive-00542459 – Intuitive-00542461; Intuitive-00642553.

[139] *E.g.*, Intuitive-02067029 (stopping testing at 13 life cycles with no failures); Intuitive-02067033 (stopping testing at 15 life cycles with no failures); Intuitive-02067034 (stopping testing at 15 life cycles with no failures); Intuitive-02067038 (stopping testing at 13 life cycles with no failures).

[140] Intuitive-00967614 at Intuitive-00967617- Intuitive-00967626.

[141] REBOTIX170053.

[142] REBOTIX170345.

uses. Rebotix also performed a second set of tests on instruments that had already been repaired by Rebotix and then tested them for a further ten life test cycles.[143] As part of that testing, Rebotix again performed the steps of its inspection and repair process before conducting the continued testing. The Rebotix results verified that after repair, the instruments did not experience failures in the additional set of ten uses.[144]

150. These results demonstrate that with proper inspection and repair after every ten uses, EndoWrist instruments can continue to be used safely. Neither Dr. Howe nor Intuitive's life testing takes these regular inspections and repairs into account.

4. <u>Comparison of Intuitive's extended life testing and the Rebotix life testing</u>

151. Dr. Howe asserts that Intuitive's life testing for the Extended Lives Program illustrates that Rebotix's life testing is inadequate because "at least one instrument of every model suffered failures by SUC [surgical use cycle] 22" (during the Intuitive testing).[145] Dr. Howe further notes that 70 failures were observed from the sample of 250 units, and that "52 of those instruments failed as a result of cable drivetrain stretch/fatigue/yield."[146] Dr. Howe claims that these failures indicate that Rebotix's life testing is inadequate. I disagree with Dr. Howe's conclusion.

152. First, the Intuitive testing of new instruments in the Extended Lives Program and the Rebotix life testing procedures are different, especially in terms of how Rebotix employs its inspection and repair process while the Intuitive testing involves no repair. As part of the Extended Lives Program, Intuitive tested instruments up to 22 surgical use cycles.[147] At no point during that

[143] REBOTIX132019.
[144] *Id.*
[145] Howe Hospital Report ¶¶ 122-125.
[146] *Id.*
[147] Intuitive-00552535.

process did Intuitive evaluate whether instruments could be repaired or serviced to allow for continued uses, or perform any such repair or service at regular intervals, as required by the Rebotix process.

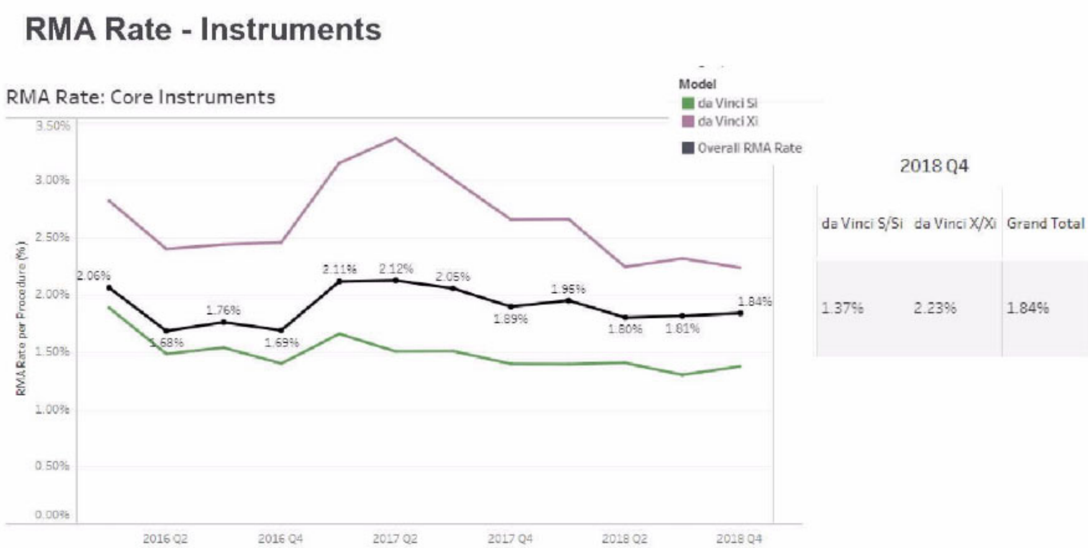
153. By contrast, Rebotix's testing assumes the proper inspection and servicing of instruments every ten uses. One round of Rebotix's life testing involved instruments that had already been used for nine uses, that were then repaired by Rebotix and subjected to a further life testing for eleven uses. Rebotix also performed a second set of tests on instruments that had already been repaired by Rebotix and used for an additional ten uses beyond the initial life counter.[148] As part of that testing, Rebotix again performed the steps of its inspection and repair process before conducting testing. The Rebotix results verified that after repair, the instruments did not experience failures in an additional set of ten uses.[149] These results demonstrate that with proper inspection and repair after every ten uses, EndoWrist instruments can continue to be used effectively with proper intuitive motion, and perform the intended function as designed. The Intuitive life testing does not perform or take these regular inspections and repairs into account. The ability to repair and reuse EndoWrists provides cost savings for the customer and reduces the frequency of disposal for EndoWrists

154. Second, Intuitive's life testing results suggest that Rebotix's repair process effectively addresses common issues that arise as instruments are used for extended periods of time. Failures due to cable and drive train stretch are addressed by inspection and tightening of cables during each Rebotix repair procedure, as described elsewhere in this report. And in the

[148] REBOTIX132019.
[149] REBOTIX132019.

event that a cable break occurs on an instrument prior to submission to Rebotix, that instrument will not be a candidate for service.

155. Although Dr. Howe previously opined that "[w]hile the Extended Live Program targeted da Vinci model X/Xi instruments, the X/Xi instruments and S/Si instruments that Rebotix performed its life testing on share enough similarities that similar life testing results would be expected,"[150] Dr. Howe now opines that since certain "component changes were not made to S/Si instruments, there is no basis to assume that those instruments would perform reliably over more than 10 uses."[151] Dr. Howe also ignores the relevant data, which shows that Si instruments had a much lower failure rate than Xi instruments when Intuitive was considering its own refurbishment program and the extended use program.[152]



[150] Expert Report of Dr. Robert Howe, *Rebotix Repair LLC v. Intuitive Surgical, Inc.,* Case No. 8:20-cv-2274-T-33TGW, dated July 26, 2021 (herein after "Howe Rebotix Report"), at ¶ 103.

[151] Howe Hospital Report ¶ 123.

[152] Intuitive-00967510 at Intuitive-00967511, Intuitive-00967513, Intuitive-00967517.

156. In other instances, Intuitive recognized that Xi 8mm instrument "life testing" could also "cover the S/Si 8mm family" based on "Instrument Design Similarities," identical "range of motion of both the S/Si and Xi instruments," "Material Compatibility," and "no differences" in reprocessing chemistry and temperatures.[153] As Dr. Howe discussed in the Howe Rebotix Report, "the X/Xi and S/Si instruments share the same drive train arrangement (e.g., four input pulleys that interface with the robot motor drive, tungsten cables that pass through the shaft to the distal wrist, and the same wrist configuration) and the distal components are considered identical for some instruments."[154]

VIII. INTUITIVE HAS NO BASIS TO CLAIM THAT ENDOWRISTS REPAIRED BY REBOTIX ARE UNSAFE.

A. To make a claim that EndoWrist repairs are unsafe, one would expect to see general testing of repairs, testing of Rebotix-repaired instruments, or identified issues caused by a repair process.

157. For Intuitive or Dr. Howe to make a claim about the safety of Rebotix's instruments,[155] there should be a basis for that claim. One basis might be that Intuitive has conducted its own testing on repairs, and concluded that repairs cannot resolve common failure modes on an instrument. This could lead Intuitive to conclude that repairs by another entity would not be feasible. Another basis could be that Intuitive or Dr. Howe examined instruments repaired by Rebotix or another repair vendor, and determined that those instruments raised safety concerns. Alternatively, Intuitive could observe and test instruments it received from hospitals that suffered failures due to the Rebotix repair process or other similar repair procedures.

[153] Intuitive-00027299- Intuitive-00027300.

[154] Howe Rebotix Report ¶ 103 (citing Intuitive-00290857 at Intuitive-00290859).

[155] *E.g.*, Howe Hospital Report ¶¶ 7, 13, 23-24, 27, 80-82, 95, 121, 123, 129, 131, 133, 135-136, 138-139, 143, 149-152, and 159-164.

158. The evidence in this case shows that neither Intuitive nor Dr. Howe took any of those steps, and therefore neither has any basis for their claims about Rebotix's instruments being unsafe. Instead, when Intuitive considered offering refurbished instruments, it concluded that those instruments could offer equivalent performance to new instruments.[156]

B. <u>None of Intuitive's extensive testing has examined the feasibility of repairing EndoWrist instruments.</u>

159. Intuitive's life testing process records failures when they occur.[157] But Intuitive has never examined whether any of those failures can be repaired. Unlike Rebotix, which performed extensive testing on whether EndoWrist instruments could continue to be safely used after the expiration of their initial use counter, Intuitive does not test whether it is possible to repair an instrument when it experiences a failure, even when that failure occurs during the initial use counter period. For example, when scissors become dull during testing, Intuitive considers that a failure. But Intuitive will not attempt to resharpen those scissors and continue testing the instrument.

Page 214
Q Now, in the process of testing, if scissors
on a pair of EndoWrist that have scissors at the end
Page 215
become dull and they're no longer cutting, that would
be a failure; right?
A Yes.
Q And that could occur at nine uses; right?
A Yes.

...

[156] DeSantis depo. (*Rebotix*) tr., 234:18 - 246:20, Intuitive-00042946, Intuitive-00603241-Intuitive-00603264.
[157] *See, e.g.* Intuitive-00546920.

> If an instrument fails because its scissors
> are dull at, let's say, eight uses, does Intuitive try
> to resharpen or in any way repair the scissors to
> determine whether the instrument can last for
> additional lives?
> A No, I don't believe so. We don't typically
> do repairs as part of our life testing.
> Q And so if an instrument failed at, say, eight
> uses because the scissors were dull, Intuitive would
>
> Page 216
>
> consider that a failure under its life testing; right?
> A Yes.
> Q Intuitive would log that and store or dispose
> of the instrument; right?
> A Yes.
> Q Intuitive would not test whether the
> instrument could continue to operate to 15 or 20 uses
> with re-sharpened scissors; right?
> A Not if our spec was ten and there was a
> failure prior to ten, no. [158]

160. For every instrument, if there is any type of failure during the life testing process, Intuitive does not attempt any repair or refurbishment of that failure.

> Page 216
>
> And that's the same for -- for other types of
> instruments as well, such as graspers or needle
> drivers; right? If there's any sort of failure,
> Intuitive doesn't attempt to repair that failure;
> right?
> A Correct. As part of our life testing
> remanufacturing, it's not part of our life testing.
> Q In fact, any sort of refurbishing repair is
> not part of life testing; right?
> A Correct.[159]

[158] DeSantis depo. (*Rebotix*) tr., 214:24 – 216:10.
[159] *Id.* at 216:12-21.

161. For each failure that Intuitive experiences in its life testing, it has never attempted repair or refurbishment. Intuitive has never examined whether loose cables can be repaired,[160] whether unintuitive motion can be repaired,[161] whether graspers can be realigned, [162] or whether the grip force on a needle driver can be repaired.[163] Refurbishment is simply not part of Intuitive's life testing process, with the exception of refurbishment project evaluation that was abandoned for profitability reasons, as I discuss later in this report. Additionally, when instruments fail after their target number of uses, Intuitive also does not perform any examination of whether that instrument can be refurbished or repaired to continue to operate safely.

> Page 216
> Q Now, if an instrument -- the desired spec for
> an instrument is ten uses and the instrument fails at
> 11 uses, Intuitive doesn't also attempt any
> refurbishment or repair of that instrument at that
> Page 217
> point; right?
> A Correct.
> Q So if an instrument, for example, failed at
> 11 uses because the scissors had dulled, Intuitive
> would not examine whether a repair could let that
> instrument operate safely; right?
> A Not typically, no.[164]

162. Even when Intuitive receives instruments from hospitals that have failed before their use counter has expired, Intuitive does not investigate whether it is possible to repair whatever

[160] *Id.* at 272:15-23.
[161] *Id.* at 277:22 – 278:11.
[162] *Id.* at 273:2-12; Vavoso depo. (*Rebotix*) tr., 235:15-18.
[163] DeSantis depo. (*Rebotix*) tr., 276:4-8.
[164] *Id.* at 216:22 – 217:7.

failure the instrument has experienced.[165] Intuitive simply categorizes those failures as part of its RMA program.[166]

C. Intuitive has not tested any instruments repaired by Rebotix, and has no basis for its assertions about the safety of those instruments.

163. Despite making numerous claims about the safety of Rebotix-repaired instruments to both hospital customers and the FDA, there is no indication that Intuitive ever tested an EndoWrist repaired by Rebotix or any other repair provider to evaluate whether it is equivalent to a new EndoWrist.

> Page 245
> Intuitive has not done testing of any kind to
> determine whether Rebotix's refurbished EndoWrists can
> safely be used with the da Vinci robot in surgery;
> true?
> A True. We've not done V&V testing, life
> testing on their instruments, no.[167]

164. Thus, Intuitive has no support for its assertions that Rebotix-repaired (or any other third-party repair provider) instruments pose risks to patients due to unintuitive motion, insufficient grip force, dull or damaged scissor blades, or worn or damaged cables. This was confirmed by Intuitive's witnesses at deposition:

1. Unintuitive motion:

> Q. Are you aware of any investigation or
> analysis by Intuitive to determine whether Rebotix's
> services caused EndoWrists to have unintuitive
> motion?
> A. I am not aware.[168]

---

[165] *Id.* at 144:10-14, 146:3-15.
[166] Intuitive-00695006.
[167] DeSantis depo. (*Rebotix*) tr., 245:6-11; *see also* Duque 30(b)(1) depo. tr., 149:9-151:8.
[168] Mark Johnson depo. (*Rebotix*) tr., 119:18-22.

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15 Q. You have no basis to assert that
16 Rebotix is unable to ensure intuitive motion
17 in EndoWrists based on the services it
18 performs, correct?
19 MS. LENT: Object to the form.
20 THE WITNESS: That's correct.[169]

2. Insufficient grip force:

23 Q. Are you aware of any investigation or
24 analysis by Intuitive that Rebotix's services caused
25 EndoWrist to have insufficient grip force?
1 A. I am not aware.[170]

----

6 You have no basis to assert that
7 Rebotix is unable to implement measures in its
8 servicing of EndoWrists to ensure that those
9 EndoWrists have sufficient grip force,
10 correct?
11 MS. LENT: Object to the form --
12 THE WITNESS: That's correct.
13 That's correct.[171]

3. Dull or damaged scissor blades:

6 Q. Are you aware of any investigation or
7 analysis by Intuitive that Rebotix's services result
8 in EndoWrists having dull or damaged scissor blades?
9 A. Nope, no[172]

----

11 Q. Has Intuitive performed any tests
12 of Rebotix repaired EndoWrist to determine if
13 they had dull or damaged scissor blades?

[169] Curet depo. (*Rebotix*) tr., 151:15-20.
[170] Mark Johnson depo. (*Rebotix*) tr., 119:23-120:1.
[171] Curet depo. (*Rebotix*) tr., 151:6-13.
[172] Mark Johnson depo. (*Rebotix*) tr., 120:6-9.

MS. LENT: Object to the form.
THE WITNESS: I don't know.[173]

Q. You don't have any basis to assert
that Rebotix can likewise take measures to
ensure that its serviced EndoWrists have
sufficiently sharp and nondamaged scissor
blade, correct?
MS. LENT: Object to form.
THE WITNESS: That's correct[174]

4. Worn/damaged cables:

Q. Are you aware of any investigation or
analysis that Rebotix's services caused EndoWrists
to have worn or damaged cables?
A. I am not aware of that.[175]

You have no basis to assert that
Rebotix does not also take measures to ensure
that the cables are not worn, not damaged, and
have sufficient tension, correct?
MS. LENT: Object to the form.
THE WITNESS: Correct.[176]

165. Hospitals that used the Rebotix repair services and were informed by Intuitive that those repaired instruments might pose safety risks asked Intuitive to provide data indicating that the instruments repaired by Rebotix were unsafe. Intuitive has never been able to provide any sort

[173] Curet depo. (*Rebotix*) tr., 153:11-15.
[174] *Id.* at 153:22-154:3.
[175] Mark Johnson depo. (*Rebotix*) tr., 120:1-5.
[176] Curet depo. (*Rebotix*) tr., 163:20-25.

of data or test results indicating that Rebotix-repaired instruments, or any Intuitive instruments repaired by other third parties, pose safety concerns.[177]

D. None of the EndoWrists that Intuitive received via the RMA process show issues caused by the Rebotix service process.

166. Dr. Howe asserts that Intuitive has observed instrument "failures" in instruments that have been repaired by Rebotix and Restore and returned to Intuitive through the RMA process,[178] and that he has reviewed purported "complaints" received by Restore.[179] Dr. Howe attempts to tie these failures to "wear and tear" or improper servicing by Rebotix and Restore. But the underlying data that Dr. Howe references shows that the failure modes on these instruments were not related to Rebotix or Restore repair procedures. In fact, the majority of the instruments referenced experienced failures due to damage and misuse during the cleaning process.

167. In the Excel spreadsheet Dr. Howe references, there are descriptions of the errors observed in EndoWrists that have had their lives extended.[180] Dr. Howe cites to several of the entries in that spreadsheet to highlight purported "failures" on instruments repaired by Rebotix. Intuitive was apparently able to detect instruments that had been repaired by Rebotix by inspecting for the Interceptor board. But a careful examination of the description of failures on those instruments reveals that the failures were not caused by the Rebotix repair process, that the instruments were functional, and that the failures did not in any instance prevent a surgery from being completed. Most importantly, there is no indication that an instrument serviced by Rebotix has caused any patient injury or harm.

[177] DeSantis depo. (*Rebotix*) tr., 270:7-10.
[178] Howe Hospital Report ¶ 77.
[179] *Id.* ¶ 78.
[180] Intuitive-00695006 at Tab 2.

1. Failures not caused by the Rebotix process

168. Failures in instruments that have had the number of lives extended were not caused by Rebotix repair procedures. Several instruments in the Intuitive RMA logs were found to have experienced a failure due to "improper cleaning."[181] Intuitive concluded that for those failures, "improper cleaning during reprocessing most commonly causes this,"[182] and there was no indication that Rebotix's services in any way caused these failures. And for the instruments that had "broken cables" as a listed failure, Intuitive concluded that "[t]his failure is most commonly caused by mishandling/misuse, such as excess force applied to the distal end of the instrument."[183] Excess force or misuse can occur at every stage of an instrument's life, including within the first ten uses. *Moreover, none of the cause of failure notes in the spreadsheet actually indicate that any of the instrument failures were believed to be a result of the Rebotix repair process*.

2. Instruments remained functional

169. Several of the other "failed" instruments had no functional issues when inspected by Intuitive. For example, four instruments cited by Dr. Howe were classified as having experienced failures because the da Vinci robot "failed to recognize" the EndoWrist.[184] The accompanying description for each of these EndoWrists shows no indication that anything else was wrong with the instrument. They also showed no sign that the failure to recognize the EndoWrist was due to Rebotix's repair process and in several cases, the report "failed to recognize" issue could not be reproduced by Intuitive. Indeed, that Intuitive's new EndoWrists sometimes fail to be recognized by the da Vinci robot appears in the Intuitive RMA log database in a number of

[181] *Id.* at Row 17, 18, 24.
[182] *Id.* at Tab 2, Row 24.
[183] *See, e.g.,* Intuitive-00695006 at Tab 2, Row 28, 29, 30, Column AB.
[184] *Id.* at Tab 2, Rows 15, 17, 44, 47.

instances.[185] In fact, it sometimes occurs with new EndoWrists during the initial set of 10 lives on the use counter. Also note that Intuitive is sometimes unable to reproduce reported incidents of "failed to recognize" on EndoWrists that have not been repaired by Rebotix. The total number of instruments repaired by Rebotix is quite limited and the number that appear in the Intuitive RMA log even more limited. Using very small datasets to infer or make statistical conclusions is not scientifically or mathematically sound. For this reason, the conclusions drawn by Dr. Howe on this data may have substantial errors.

170. Further, Intuitive was often unable to replicate the customer's concerns. For example, Row 17 contains an instrument for which Intuitive was unable to replicate the concerns expressed by the customer. The instrument was attached to the Si robot, no error messages or faults appeared, the pins did not stick and were not contaminated, and the EndoWrist was driven and moved intuitively.[186]

3. <u>In cases where failures occurred, no adverse effect on the patient</u>

171. The spreadsheet Dr. Howe references contains 24 instruments in the United States that had their useful lives extended before being returned to Intuitive through the RMA process. Of those instruments, 7 experienced some sort of issue during the surgical procedure, each of which was completed successfully with no patient injury or adverse event.[187]

[185] *See, e.g.,* Intuitive-00695006, Tab 1, 15506, 60952, 68890, 70768, 131231.
[186] Intuitive-00695006, Tab 2, Row 17.
[187] Intuitive-00695006, Tab 2, Rows 28, 29, 30, 31, 44, 45, 46.

4. The purported "failures" of Restore-repaired EndoWrists were not failures, or were the result of misuse.

172. Dr. Howe also refers to "evidence produced by Restore of complaints it received from customers relating to failure of instruments which had usage limits extended."[188] However, none of the purported failures was due to a mechanical error that stemmed from using it past Intuitive's use limits, or from Restore's repair process. [redacted]."[189] [redacted].[190]

5. There has been no indication that the use of any instrument serviced by Rebotix or Restore has caused any patient harm.

173. Since Rebotix and Restore began offering their services in the United States in 2019 and 2018, respectively, I have seen no evidence that the instruments repaired by Rebotix or Restore have caused any adverse event or resulted in any patient harm. Dr. Howe does not identify any such evidence, or argue otherwise in his report.

E. When Intuitive briefly considered developing refurbished EndoWrists, it did not conclude that refurbished EndoWrists would be unsafe. Intuitive chose not to pursue refurbishment because that program would not be profitable for Intuitive.

174. Intuitive considered a program to refurbish EndoWrists in 2017.

> 2 I understand that in 2017 Intuitive
> 3 considered refurbishing EndoWrists; is that right?
> 4 A Yes.[191]

[188] Howe Hospital Report ¶¶ 78-79.
[189] Restore-00030379.
[190] Restore-00001424-Restore-00001439.
[191] DeSantis depo. (*Rebotix*) tr., 227:2-4.

175. Those refurbished instruments would have equivalent performance to new instruments, and would have the same use counter as new instruments.

> Page 236
> Q Under "Clinical Performance," the first
> bullet point reads "Equivalent performance" right?
> A Yes.
> Q Do you understand that to mean refurbished
> instruments would have new equivalent performance to
> new EndoWrist?
> A Yes. We wouldn't release instruments to the
> field that had inferior performance than our specs.
> Q And the second bullet point is:
> "10 lives per instrument."
> Right?
> A. Yes.
> Q That would mean the refurbished instruments
> would have a 10-life use counter on them as well;
> right?
> A Yes, according to the slide.[192]

176. And Intuitive concluded that refurbished instruments could provide equivalent performance to new instruments.

> Page 237
> Q As of April 11, 2017, was it your
> understanding that refurbished instruments could
> provide equivalent performance to new instruments?
> A Yes.[193]

177. Dr. Howe contends that Intuitive ultimately did not implement a refurbishment program because it would have needed to demonstrate the reliability of the refurbished instruments

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[192] *Id.* at 236:5-20.
[193] *Id.* at 237:16-19.

and the cost associated with part replacements necessary to achieve that reliability became "cost prohibitive."[194] To the contrary, Intuitive ultimately decided not to pursue an instrument refurbishment program because the program would not be more profitable than selling new EndoWrists, *not* because the instruments were unsuitable for refurbishment.

> Page 266
> Now, ultimately Intuitive did not pursue an
> instrument refurbishment program for the da Vinci Si
> or for the da Vinci Xi; right?
> A Not to date.
> Q It's because instrument refurbishing, that's
> something that's not profitable for Intuitive; right?
> A Yeah. Financially it turned out to be
> essentially a wash between building new instruments
> and going through the entire process of collecting and
> remanufacturing to original specs, et cetera.[195]

178. Contrary to Dr. Howe's assertion that Intuitive "determined that the cost associated with part replacements necessary to achieve that reliability became 'cost prohibitive[,]'" the primary cost drivers for the refurbishment program were the cost to collect instruments and the cost of labor. For collection, Intuitive "looked at other companies that did collections and that cost was [excessive], it was -- it was unbelievable how much that cost was to have a company go do that."[196] Refurbishment could be performed for substantially less than a new build in Intuitive's Mexicali facility,[197] but not in the United States,[198] because for refurbishment "the cost of the instruments was labor, it wasn't the material, it was labor."[199] It should also be noted that labor

[194] Howe Hospital Report ¶ 134.
[195] DeSantis depo. (*Rebotix*) tr., 266:1-10.
[196] Morales 30(b)(6) depo. tr. 24:24-26:10.
[197] Morales 30(b)(6) depo. Ex. 143, Intuitive-00626597 at Intuitive-00626613.
[198] *Id.* at Intuitive-006265611-12.
[199] Morales 30(b)(6) depo. tr. 29:24-30-3, 58:3-60:4.

costs in the Intuitive proposed refurbishment program was increased dramatically by the plan to replace many parts of the EndoWrists (cables, pulleys, etc.), without determining whether that was even necessary. The Intuitive refurbishment program basically involved disassembling a returned EndoWrist, and then reassembling it with many new components. Overall, the Rebotix repair process and the proposed Intuitive refurbishment program are quite different and have significantly different associated costs. The Rebotix repair process is designed to be cost-effective in comparison to the cost of new EndoWrists.

179. Dr. Howe also nonsensically states that "Intuitive replaced the EndoWrist cables during its refurbished instrument testing process but still observed broken cables during life testing."[200] From this he posits that "Intuitive concluded that safely and reliably refurbishing EndoWrist instruments required replacing components of the instruments, not simply sharpening them and manually adjusting cables."[201] Dr. Howe's conclusion does not follow from the cited document, which says nothing about whether replacing cables provides better results than tensioning the previously installed cables.[202] Rather, that document merely confirms that, like Intuitive new builds, cable failures may still occur during testing. It is important to note that the repair processes developed by both Iconocare and Rebotix do not involve replacement of cables, pulleys, etc. Even on newly manufactured EndoWrists, the Intuitive RMA data shows substantially higher failures of all types in the early stage of the rollout. This is common and generally anticipated in the introduction of new products, new designs, or new materials.

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[200] Howe Hospital Report ¶ 138.
[201] *Id.*
[202] Intuitive-00626429 at Intuitive-00626431–32.

IX. DR. HOWE SIMILARY HAS NO BASIS FOR ASSERTING THAT INSTRUMENTS REPAIRED BY REBOTIX ARE UNSAFE.

A. Appropriate conclusions about the safety of an instrument can be drawn from an examination of the instrument or an examination of all relevant information about how the instrument is serviced.

180. In my experience as a mechanical engineer, I have previously assessed potential safety concerns with service procedures or instrument repair processes. In performing this analysis, I will either directly examine the repaired device in question and the accompanying service process, or I will consider the entire documentation that details the service procedure.

181. Dr. Howe took neither approach. Instead, he attempted to draw conclusions about the safety and reliability of the Rebotix repair process from a general document (the EndoWrist Service Procedure) and a single video of a repair procedure being performed.[203] Dr. Howe used these sources to conclude that "significant problems exist with Rebotix's approach" to repairing EndoWrists[204] and that the procedures "pose risks to both instrument functionality as well as patient safety."[205]

182. There are at least two problems with Dr. Howe's evaluation of the Rebotix procedures. First, Dr. Howe has never examined nor tested an EndoWrist repaired by Rebotix or any other third party. Second, Dr. Howe did not consider or examine the underlying, detailed procedure documents that provide additional detail about the Rebotix repair process. The Rebotix process is comprehensive and well-documented, starting with the essential incoming inspection to

[203] Howe Hospital Report ¶ 82.
[204] *Id.* ¶ 80.
[205] *Id.* ¶ 82.

determine feasibility of repair. Rebotix does not attempt to repair EndoWrists that have several different types of damage or wear which make them unsuitable for repair.

B. <u>Dr. Howe has no experience with EndoWrists repaired by Rebotix.</u>

183. Just like Intuitive, Dr. Howe has never done any testing on EndoWrists repaired by Rebotix or any other third party. Dr. Howe has not (a) compared an EndoWrist repaired by Rebotix, Restore, or other third-party-repaired EndoWrist to a new instrument, (b) inspected an Rebotix, Restore, or any third-party for cable wear, or (c) examined the current practices of Rebotix, Restore or any other third party in repairing its instruments.

184. Instead, Dr. Howe speculates about potential safety concerns, while ignoring relevant facts and testimony in the case. For example, Dr. Howe speculates about the number of failures suffered by repaired instruments on no more than the basis of the total repaired instruments sold by third parties.[206] But Dr. Howe never considers testimony by hospital representatives that EndoWrists repaired by Rebotix functioned identically to new Intuitive EndoWrists, and that they have not suffered failures during medical procedures.[207]

185. Dr. Howe's lack of experience with Rebotix instruments is reflected in his misunderstanding of various aspects of the Rebotix repair process. For example, Dr. Howe asserts that "particulate debris" is generated by the procedures and methods developed by Rebotix, that "inadequate methods are prescribed" for dealing with that particulate debris,[208] and that "methods for thoroughly removing this debris are not provided in the Rebotix Process."[209]

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[206] *See, e.g.,* Footnote 128, "While I do not have complete information on the number of failures that occurred among EndoWrist instruments that had usage lives extended by Restore, I would expect the actual number of failures to be higher."

[207] Harrich depo. (*Rebotix*) tr., 38:9-39:9, 40:2-8, 43:2-19.

[208] Howe Hospital Report ¶ 89.

[209] *Id.* ¶ 148.

186. Dr. Howe asserts that "blowing on the instrument" and "brushing the instrument" are not adequate means to effectively remove debris.[210] However, Dr. Howe does not consider the extensive cleaning process that occurs before the instrument is shipped back to the hospital. That process is detailed in the cleaning and sterilization protocols that are present at the station staffed by the Rebotix technician as part of evaluating incoming EndoWrists. Also, the instruments are further sterilized and reprocessed at the medical center after being returned from Rebotix and before they are used in any surgical procedure.

Photograph taken at Rebotix facilities on August 10, 2021.

[210] *Id.* ¶ 89.

187. The cleaning and reprocessing steps include an ultrasonic cleaning, flushing of the instrument tubes, drying, lubrication, and disinfection. And while the hospital itself re-sterilizes the EndoWrist after receiving it back from Rebotix, Rebotix nonetheless sterilizes the instrument to ensure that there are no contaminants prior to shipment. This process of cleaning prior to shipping the instrument back to the hospital also resolves any concerns with the "shop air" that Dr. Howe claims may introduce contamination to the instrument.[211]

C. <u>Dr. Howe only points to the general Rebotix service description, but ignores the underlying documents that are referenced.</u>

1. <u>Rebotix has general service documents that reference underlying documentation for more specificity.</u>

188. The complete set of Rebotix repair procedures are not contained in a single document. Instead, details about the individual steps in a repair procedure are contained in a number of underlying documents, which are frequently cross-referenced. As one example, a Rebotix document that describes the final testing of EndoWrists prior to being shipped back to the customer provides a general description of the testing process.[212] That document then references a number of underlying documents that provide more detail about the underlying steps.

6.0 Perform Degree of Freedom test per SOP PR3039.
7.0 Perform Cutting Efficiency Test per SOP PR3038 (Models with scissors or blades only)
8.0 Perform Gripping Efficiency Test per SOP PR3037 (Grasper and Needle Driver Models only).
9.0 Perform Hipot Test per SOP PR 3041.
10.0 Perform DC Resistance Test per SOP PR3042. Monopolar, Bipolar and PK units only
11.0 Perform device recognition test per SOP PR3008. Verify that Lot / Serial # on screen matches the traveler and housing. Verify that the device make and number of remaining uses is correct.

REBOTIX123448

[211] Howe Hospital Report ¶ 97.
[212] REBOTIX123448.

189. A technician seeking to perform a "Degree of Freedom" test would reference the document SOP PR3039, which provides extensive additional detail on how to test the various EndoWrist degrees of freedom. For example:

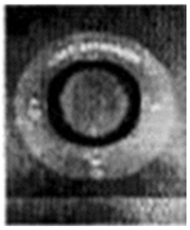
5.0 PROCEDURE;

5.1 Setup

5.1.1 Turn on the Optical Comparator using the green rocker switch located near the base

5.1.2 Turn on the QM-Data 200 using the green illuminated switch on the back of the unit.

5.1.3 Make sure the Light Exchanger dial is in the center position (profile and surface illumination).



5.1.4 Before first EndoWrist measurement of the day, refer to W13039 to perform a measurement verification of the Optical Comparator and QM-Data 200 using a calibrated angle block.

5.1.5 With the green shaft clamp open and the wheel manipulation plate off, load the EndoWrist into the fixture upside down. Make sure the EndoWrist tabs on the main body mate properly and are fully engaged so that all rotation wheels are completely visible.

5.1.6 Place PRI 151-004 Disc Isolator Plate 4 onto the EndoWrist.

5.1.7 Use the large grey dial to raise or lower the comparator table and fixture until the EndoWrist shaft is centered in the viewer.

5.1.8 Use the release tabs and the black dial on the right side of the table to center the tool end of the EndoWrist in the viewer.

5.1.9 Ise the black dial on the loft side of the table to focus the image in the viewer.

5.2 Measure Pitch 3 Degree of Freedom.

5.2.1 Ensure that Rotation Wheel 4 is in Neutral Position and lock down green clamp onto shaft.

REBOTIX085489-REBOTIX085491

5.2.2 Center the Image crosshairs on the Wrist Clevis Pin.
5.2.3 Using the QM Data or the Overlay, ensure that the Tool Clevis is at 0° +/- 5°.
5.2.4 Remove Disc Isolator Plate 4.
5.2.5 Manipulate Wheel 3 by hand and ensure that the Tool Clevis travels the full Degree of Freedom until its mechanical stops of the Wrist Clevis without any clicking, snagging, or artificial stops.

5.3 Measure Yaw 1 & 2 Degree of Freedom.
5.3.1 Release the green clamp and rotate the shaft 90°. Lock the green clamp back onto the shaft.
5.3.2 Place Disc Isolator Plate 4 back onto EndoWrist Wheels.
5.3.3 Center the Image Crosshairs on the Tool Clevis Pin.
5.3.4 Using the QM Data or the Overlay, ensure that the Tool End of the EndoWrist is at 0° +/- 5°.
5.3.5 Remove Disc Isolator Plate.
5.3.6 Manipulate Wheel 1and 2 by hand and ensure that the Tool End of the device travels the full Degree of Freedom until it reaches the Tool Clevis mechanical stops without any clicking, snagging, or artificial stops.

5.4 Complete applicable paperwork and refer to PR3048 Process Flow Chart.

REBOTIX085489-REBOTIX085491

190. Similarly, a technician performing the "Hipot Test" described in step 9.0 would reference the detailed instructions in PR 3041 Dielectric Testing SOP.

5.0 PROCEDURE:

5.1 Monopolar Cautery EndoWrist Dielectric Testing Procedure.

5.1.1 Turn On Hipot Tester.
5.1.2 Configure the Hipot testing to the parameters listed in Table 1. Note: These parameters can be stored into memory for quick recall.

Test Type	ACW
Voltage	2.83kV
Max Lmt	2.00mA
Min Lmt	0.010mA
Ramp UP	0.1s
Dwell	30.0s
Ramp DN	0.0s
Arc Sense	0
Frequency	60Hz
Continuity	OFF
Max Lmt	1.00Ω
Min Lmt	0.00Ω
Offset	0.00Ω
Connect	OFF

Table 1 ***Hipot Tester Settings for Monopolar Cautery EndoWrist***

5.1.3 Place the EndoWrist into the PR1107 Hipot Test Fixture. Configure the Hipot Test Fixture to accommodate the EndoWrist under Test, using the front spacer for reference #'s 420183 and 420184.

Page 1 of 5

5.1.4 Clamp the top of Hipot Tester down so that the shaft is securely in place in the Hipot tester.
5.1.5 Connect the black lead from the Hipot tester to the metal stud on the top of the Hipot Test Fixture.
5.1.6 Connect the red lead from the Hipot tester to the Monopolar connection on the back of the EndoWrist.
5.1.7 Activate the Hipot tester by pressing the Green button on the front of the Hipot Tester. Use care not to touch the device during testing, a shock could result.
5.1.8 The device will be tested for a period of 30sec. If at any point during the testing, a breakdown occurs, the Hipot Tester will alarm.
5.1.9 If the EndoWrist under test passes, the Hipot tester will indicate pass.
5.1.10 Remove the EndoWrist from the Hipot Test Fixture.

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191. Each of the other steps in the Rebotix process is similarly described in detail as to how it is to be performed.

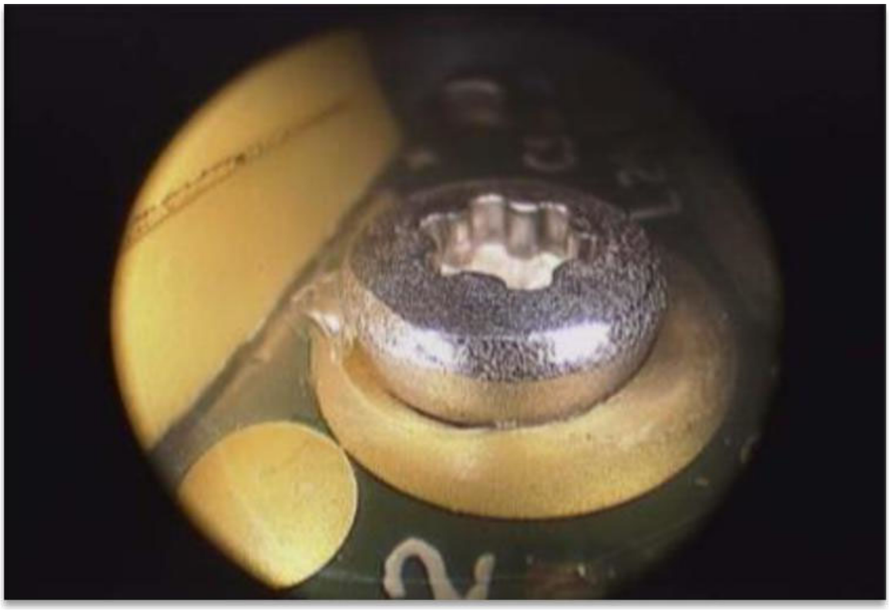
2. <u>Dr. Howe consistently ignores these underlying procedure documents when he makes generalized assertions about Rebotix's service procedures.</u>

192. Dr. Howe did not consider all of the available Rebotix service materials, which resulted in his misunderstanding and mischaracterizing aspects of the Rebotix repair process. For example, Dr. Howe asserts that Rebotix does not take steps to guard against inadequate holding force on the PCB mounting clips.[213] But this risk is expressly accounted for in Section 6.5.11 in the Rebotix service process.[214] In addition, Rebotix adds a screw near the flex board that provides for additional mechanical fixation of the Interceptor assembly to the EndoWrist housing.[215]

[213] Howe Hospital Report ¶ 90.

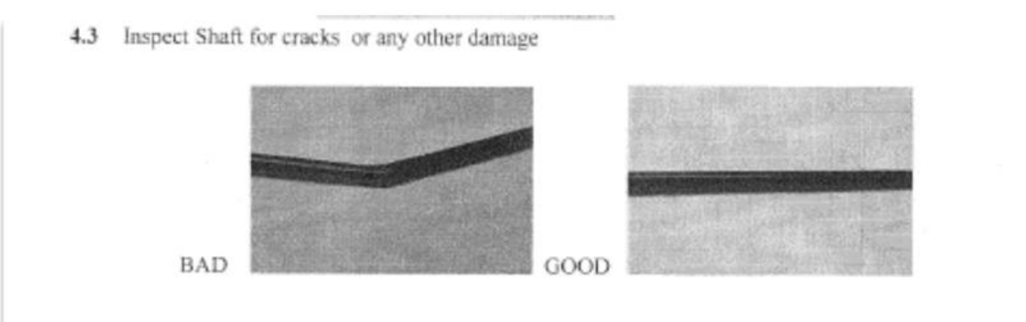
[214] "Verify the PCB is held firmly in place, and does not move when the pins are pressed on." REBOTIX162444.

[215] REBOTIX160706



REBOTIX170136

193. As another example, Rebotix's repair procedure for evaluating incoming EndoWrists (PR3043) clearly informs technicians to "inspect [EndoWrist] Shaft for cracks or any other damage."[216]



REBOTIX121303

194. The inspection includes both external mechanical damage, and electrical tests that can detect any damage to the integrity of the main instrument tube.

[216] REBOTIX121303.

195. As a third example, Rebotix specifies that its TheraBand material is a particular type of material ordered only from a specific and approved manufacturer.[217] And Rebotix inspects the TheraBand material before using it in testing the cutting capability of sharpened scissors.[218]

196. Further, Rebotix's "PR3038 Testing the Cutting Efficiency of EndoWrist Scissors SOP" clearly specifies how the TheraBand material is used in the sharpening and testing process:

TITLE: PR3038 Testing the Cutting Efficiency of EndoWrist Scissors SOP

1.0 PURPOSE:
This document provides the procedure for testing the cutting efficiency of DaVinci EndoWrists.

2.0 SCOPE:
This procedure applies to DaVinci EndoWrist Scissors.

3.0 APPLICABLE DOCUMENTS:
3.1 DIN 58298
3.2 PR3047 Test Form
3.3 PR3048 Process Flow Chart

4.0 PROCEDURE:
4.1 Inspect the blades under 10X magnification:
4.1.1 There should be no defects present on the cutting surface of the blades or the entire blade assembly. The cutting edge should be sharp and burr free.
4.1.2 Like parts must be symmetrical in size and shape.
4.2 Using PR1138-002 TheraBand control material, make 3 continuous cuts across 2/3 of the cutting length of the scissors, without exerting any lateral pressure:
4.2.1 It must be possible to separate the test material smoothly, and without it slipping or snagging on the blades.
4.2.2 The scissors should not stick while cutting.
4.3 Complete applicable paperwork and refer to PR3048 Process Flow Chart.

REBOTIX134642

197. Dr. Howe failed to consider any of these underlying documents in assessing the safety of Rebotix's repair process.

[217] REBOTIX153047.
[218] *Id.*

D. Rebotix's Cable Tensioning Procedure

198. While Dr. Howe repeatedly criticizes Rebotix's cable tensioning procedures,[219] his criticism is flawed and not based on the entire cable tensioning procedure developed by Rebotix.

199. The purpose of cable tensioning is to avoid the results of a cable being too tight or too slack. When a cable is too tight, the wheels on the bottom of the EndoWrist require additional torque to move the cables, resulting in unintuitive or rough motion. Similarly, when a cable is too slack, the EndoWrist cable system does not accurately transmit the motions from the surgeon console to the end of the EndoWrist instrument, resulting in unintuitive motion. The only reason for identifying a specified tension number for the cable is that the tension value generally correlates to a device that is not exhibiting the results of the drive cable being too slack or too tight. However, it is the condition of the cable that matters, not the number itself. Adjusting to a number is only a sign that the tension is likely correct; it does not assure that the too tight or too slack conditions are not occurring. The only way to determine whether too tight or too slack conditions are occurring is to directly test for those conditions on each device. The Rebotix repair process performs this evaluation on each device.

200. The Rebotix repair process directly tests the result of the cable tension to see that the conditions that would result from the drive cable being too tight or too slack are not present.

201. Moreover, Rebotix confirmed that its cable tensioning procedures were appropriate during its extensive EndoWrist testing. In its original testing, Rebotix determined the desired range for the no load torque values for the mechanical wheels at the bottom of the EndoWrist and quantified each of those values. The Rebotix life testing protocols established

[219] Howe Hospital Report ¶¶ 94-95, 103.

calibration of the no-load torque for each drive wheel in both clockwise and counterclockwise directions, and specified the range of motion of each EndoWrist wheel. In the image below, Rebotix discusses calibration for each mechanical wheel on the EndoWrist (identifying specific values) and describes the mechanical degree of freedom expected of the jaws of the device.

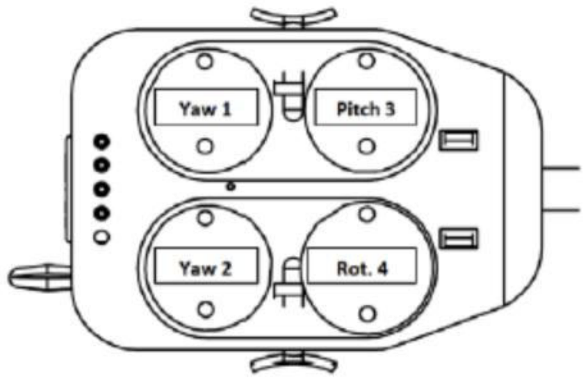


Figure 1

<u>mechanical_wheel_no_load_torque_yaw_2</u>

The no load torque of the Yaw 2 wheel shall be calibrated to 3.0 – 7.0 in. oz f. of torque. (Clockwise and counterclockwise wheel rotation). Refer to figure 1 for identification of the Yaw 2 wheel.

<u>mechanical_wheel_no_load_torque_pitch_3</u>

The no load torque of the Pitch 3 wheel shall be calibrated to 3.0-6.8 in. oz f. of torque in the clockwise wheel rotation. The no load torque of the Pitch 3 wheel shall be calibrated to 4.2-10.7 in. oz f. of torque in the counter-clockwise wheel rotation. Refer to figure 1 for identification of the Pitch 3 wheel.

<u>mechanical_wheel_no_load_torque_rotation_4</u>

The no load torque of the Rotation 4 wheel shall be calibrated to .25-2.0 in. oz f. of torque. (Clockwise and counterclockwise wheel rotation). Refer to figure 1 for identification of the Rotation 4 wheel.

<u>mechanical_degree of freedom_yaw</u>

The jaws of the device shall move freely (without binding or slipping) in the Yaw directions (clockwise and counter-clockwise) to the tool clevis mechanical stops (See Figure 2) when the Yaw 1 and Yaw 2 wheels are rotated in both directions.

REBOTIX170067

202. The PR3052 Spool Torque SOP shows the different no load torque values specific to each EndoWrist's clockwise and counter-clockwise wheel movement.

Ref	EndoWrist	Yaw 1 in. oz f.		Yaw 2 in. oz f.		Pitch 3 in. oz f.		Rotation 4
		Clockwise	Counter Clockwise	Clockwise	Counter Clockwise	Clockwise	Counter Clockwise	Both Ways
420001	Potts Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420006	Large Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420007	Round Tip Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420036	Debakey Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420048	Long Tip Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420049	Cadiere Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420093	ProGrasp Forceps	2.0 - 4.6	2.4 - 5.6	2.0 - 4.0	2.6 - 5.0	2.0 - 6.5	4.3 – 9.7	.25 – 2.0
420110	Precise Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420171	Micro Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420172	Maryland Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420178	Curved Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420179	Monopolar Curved Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420181	Resano Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420183	Permanent Cautery Hook	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420184	Permanent Cautery Spatula	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	.25 – 2.0
420189	Double Fenestrated Graspers	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	.25 – 2.0
420190	Cobra Grasper	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420194	Mega Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420205	Fenestrated Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420207	Tenaculum Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420227	PK Dissecting Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420296	Large SutureCut Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420309	Mega SutureCut Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420344	Curved Bipolar Dissector	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0

Table 1

PR3052 – Wheel No Load Torque; REBOTIX133349

203. As part of that testing of wheel no load torque values, Rebotix examined the cable tension that is required to achieve the desired intuitive motion of each EndoWrist. And Rebotix

concluded that when it tightened the cables enough to remove the slack from the cables, the wheel torque values were in an acceptable range, and more importantly, its repaired EndoWrists functioned equivalently to new EndoWrists sold by Intuitive.[220] The no load torque values are checked for each wheel in both directions to confirm that the torque values are within range, that there is intuitive motion, and that the response is smooth and without roughness.

204. Rebotix then tested wheel no load torque values over multiple uses to determine whether those values were altered by the use and whether any cable tension issues developed during the testing. For example, in the second round of life testing (life testing performed on instruments that had already been repaired by Rebotix once), Rebotix measured wheel no load torque values on each of the tested EndoWrists to ensure that they remained within an acceptable range after an additional eleven uses. These values are recorded on the data sheet for the life testing associated with each repaired EndoWrist (see examples below) selected for the life testing protocol. The wheel torque values exhibited what Rebotix also verified during its manual testing: the instrument cables performed their function and each EndoWrist moved intuitively and smoothly.

[220] Greg Fiegel conversation, *see also* REBOTIX124900-REBOTIX124923, REBOTIX120686.

Attachment D: Test Record

Test Performed By: ______ Date(s): 2/20/15 - 3/6/15 Test Sample #: 22

ACTION	Pretest	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Post-Life
Correct Audible Tones (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Correct LED color (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Uses Remaining displayed (9.5, 9.11)	11	11 ✓	10 ✓	9 ✓	8 ✓	7 ✓	6 ✓	5 ✓	4 ✓	3 ✓	2 ✓	1 ✓	0 ✓
Picture of screen, Surgery (9.5, 9.11)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Jaw Open Angle (9.5, 9.11)	38	38	38	38	38	38	38	38	38	38	38	38	38
Tool Efficiency (9.5, 9.11)	P												P
Movements, Pitch Up (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Pitch Down (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Left (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Right (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CCW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Grips (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, LOT (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Description (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Uses Remaining (9.7)		10 ✓	9 ✓	8 ✓	7 ✓	6 ✓	5 ✓	4 ✓	3 ✓	2 ✓	1 ✓	0	
Picture of screen, Inventory (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Scrub (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Flush (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Ultrasonic Cleaning (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Autoclave Sterilization (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Visual Inspection (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Hipot (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Picture of Tool End (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Shaft (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of PCBA (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Screw (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side1 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side2 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Laser Etching (9.2, 9.9, 9.11)	✓												—
Wheel Torque, Yaw 1 CW (9.3, 9.11)	3.7												3.5
Wheel Torque, Yaw 1 CCW (9.3, 9.11)	3.6												3.3
Wheel Torque, Yaw 2 CW (9.3, 9.11)	3.4												3.4
Wheel Torque, Yaw 2 CCW (9.3, 9.11)	3.4												3.3
Wheel Torque, Pitch 3 CW (9.3, 9.11)	3.3												3.1
Wheel Torque, Pitch 3 CCW (9.3, 9.11)	3.6												3.5
Degree of Freedom, Tool End (9.3, 9.11)	P												P
Degree of Freedom, Tool Clevis (9.3, 9.11)	P												

REBOTIX132562

Attachment D: Test Record

Test Performed By: ______ Date(s): 2/20/15 - 3/6/15 Test Sample #: 21

ACTION	[illegible]	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Post-Life
Correct Audible Tones (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Correct LED color (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Uses Remaining displayed (9.5, 9.11)	11	11	10	9	8	7	6	5	4	3	2	1	0
Picture of screen, Surgery (9.5, 9.11)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Jaw Open Angle (9.5, 9.11)	36	38	38	39	38	38	38	39	39	38	38	38	36
Tool Efficiency (9.5, 9.11)	✓												P
Movements, Pitch Up (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Pitch Down (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Left (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Right (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CCW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Grips (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, LOT (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Description (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Uses Remaining (9.7)		10	9	8	7	6	5	4	3	2	1	0	
Picture of screen, Inventory (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Scrub (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Flush (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Ultrasonic Cleaning (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Autoclave Sterilization (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Visual Inspection (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Hipot (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Picture of Tool End (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Shaft (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of PCBA (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Screw (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side1 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side2 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Laser Etching (9.2, 9.9, 9.11)	✓												✓
Wheel Torque, Yaw 1 CW (9.3, 9.11)	3.2												3.2
Wheel Torque, Yaw 1 CCW (9.3, 9.11)	3.4												3.4
Wheel Torque, Yaw 2 CW (9.3, 9.11)	3.6												3.5
Wheel Torque, Yaw 2 CCW (9.3, 9.11)	3.1												3.2
Wheel Torque, Pitch 3 CW (9.3, 9.11)	3.8												3.7
Wheel Torque, Pitch 3 CCW (9.3, 9.11)	3.9												3.6
Degree of Freedom, Tool End (9.3, 9.11)	P												P
Degree of Freedom, Tool Clevis (9.3, 9.11)	P												P

REBOTIX132559

E. Rebotix's Visual Inspection

205. Dr. Howe asserts that Rebotix's inspection methods are over-generalized and insufficient. But contrary to Dr. Howe's assertion that Rebotix provides technicians "no guidance on what the full intended range of motion should be,"[221] Rebotix clearly specifies what a full range of motion for the mechanical wheels should be.[222]

[221] Howe Hospital Report ¶ 96.
[222] REBOTIX133349.

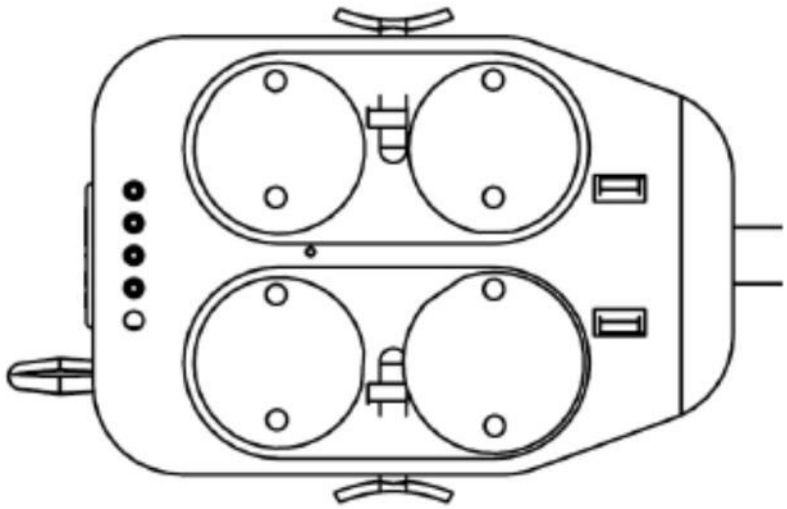


Figure 4

__mechanical_degree_of_freedom_rotation__

The device shall be capable of a rotational degree of freedom whereby the rotation wheel tab meets the full mechanical stop against the main body in both clockwise and counter-clockwise orientations.

REBOTIX170069

206. Further, the visual inspection of the EndoWrist inspects the components in the proximal housing, and verifies that the cables are functioning properly and free of fraying or breakage inside this housing. It also verifies that the cables are properly engaging with the pulleys.[223]

[223] *See, e.g.,* REBOTIX162442-162443.

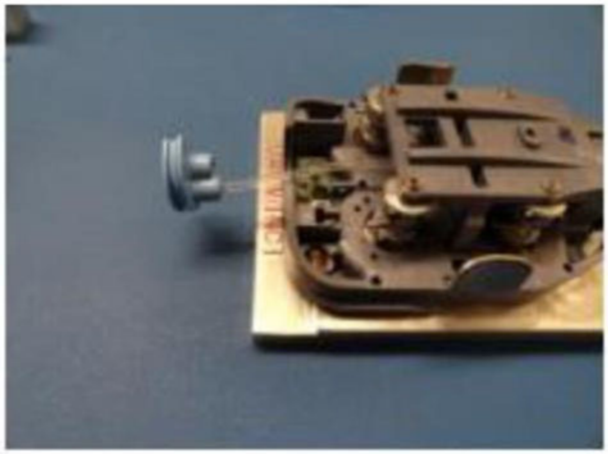
207. Dr. Howe also asserts that the Rebotix repair process "could result in loose parts that interfere with operation of the cable drive components in the proximal housing."[224] This statement ignores numerous inspection steps to ensure this doesn't happen.

208. For example, Steps 6.4.1.2 and 6.4.1.3 require the operator to "evaluate cable movements in the housing and how the cable wraps around the cable spool."[225]

209. The accompanying images show the components in the proximal housing during adjustment and inspection steps:

REBOTIX162441

[224] Howe Hospital Report ¶ 90.
[225] REBOTIX162442-REBOTIX162443.



REBOTIX162439

F. <u>Rebotix's Electrostatic Discharge Precautions And "Shop Air"</u>

210. Contrary to Dr. Howe's assertions,[226] the Rebotix service procedure expressly includes instructions about electrostatic discharge.

1.4.1. Handling PCB Assemblies

The PCB assemblies contain components that are sensitive to static electricity. When handling PCB assemblies, you must take precautions to avoid damaging the components (ESD protection).

Always use a grounded wristband and grounded work surface when working with ESD sensitive components. Adequate service tools must also be used.

PCBs (new or exchanged parts) must always be kept in protective packaging for ESD sensitive devices when not being worked on.

Remove and insert the PCBs carefully to avoid damage to the PCB and its components.

REBOTIX162405

[226] Howe Hospital Report ¶ 97.

211. And, as discussed above, the ultrasonic cleaning process that the instrument is subjected to prior to being shipped back to the hospital addresses any potential contamination that would result from "shop air."[227]

X. INADEQUACIES OF THE ENDOWRIST USE COUNTER

212. Dr. Howe asserts that the use counter is an "essential part of the specifications for the EndoWrist instruments"[228] that ensures that EndoWrists can be used safely.[229] This assertion is false and ignores many aspects of the use counter implementation and operation by Intuitive. The paragraphs below discuss the use counter limitations in detail.

213. First, although Dr. Howe contends that the Rebotix repair process does not address "wear and tear,"[230] it is actually the Intuitive EndoWrist use counter that merely measures how many times an instrument has been "used" in a surgery, as opposed to the wear the instrument experiences during the surgery. An instance of "use" itself is poorly correlated with wear, because it does not take into account the time or complexity of the "use" or surgery. Intuitive relies merely on the number of "uses," even though it measures and stores data that could easily be used to more accurately measure actual usage data, e.g., actual length of time and intensity of the EndoWrist usage during a surgical procedure. As a result, the use counter artificially cuts short the useful life of EndoWrists.

214. Second, although Dr. Howe contends that "[a]n essential part of the specifications for the EndoWrist instruments is a limitation on the number of times each instrument can be used

[227] *See, e.g.,* REBOTIX162422.
[228] Howe Hospital Report ¶ 33.
[229] *Id.* ¶¶ 8, 10, 13, 27, 64, 80, 132.
[230] *Id.* ¶¶ 19, 100, 102, 108.

for surgical procedures,"[231] Intuitive's use counter does not account for the mishandling or misuse of an instrument should it occur. An instrument can fail due to mishandling on its first use or on its twentieth. Inspection by surgical staff at the medical center is required to identify damage due to mishandling. If not identified by the surgical staff, the instrument may demonstrate problems during the surgical procedure, thus necessitating an instrument replacement during the procedure.

215. Third, although Dr. Howe contends that Intuitive "has conducted rigorous testing and identified a maximum use limit for Endowrists,"[232] and that its EndoWrist "designs are life tested[,]"[233] Intuitive did not adequately perform failure mode testing. Rather, Intuitive's initial life testing merely validated a preset target provided by its marketing department. This early testing did not attempt to establish statistically (with a given reliability and confidence levels) the maximum number of uses an instrument could actually undergo before experiencing a failure. The marketing department targeted 10 uses for most of the Si EndoWrist instruments. All testing that was done related to the 10-use limit was directed toward showing that the specified number of 10 uses could indeed be obtained to a high degree of reliability and confidence, absent any mishandling of the device. This testing did not attempt to (a) determine the maximum life for the EndoWrists under the test conditions, or (b) explore failure conditions or which components were most likely to fail. The testing never also evaluated any feasibility of repair at any specified number of testing cycles. Intuitive documents indicate that the first time any EndoWrist devices were tested to failure and documented occurred during the Extended Lives Program described earlier.

[231] Howe Hospital Report ¶ 33.
[232] *Id.* ¶ 8.
[233] *Id.* ¶ 44.

216. Fourth, although Dr. Howe contends that "maximum use limit ensures that instruments perform safely and reliably,"[234] the use counter indicates only that the proximal end of the EndoWrist, which contains the use counter chip, was mounted to the da Vinci robot and entered into "following" mode, thus recording a use and decrementing the use counter. There is no check on the condition of the instrument or an assessment of the instrument's operation; those checks must be performed by the hospital team. The shaft and distal tool end could be totally removed from the instrument and the use counter would still be decremented if the surgeon attempted to operate the instrument. In this sense, the use counter is meaningless as an indicator of safe operation for any EndoWrist.

A. <u>Use counter does not measure actual wear experienced by instruments in surgeries.</u>

1. <u>Surgical procedures vary radically in amount of time and complexity, and therefore result in different amounts of load and stress placed on each instrument used during surgery.</u>

217. All surgeries, including laparoscopic surgeries, range significantly in the amount of time and intensity involved in the procedure. For example, one study highlighted that the "range of operating times is great," and that there is a "relative lack of predictability in procedure times." The study concluded that timing for the most common gynecological laparoscopic procedures ranged between 10 and 400 minutes.[235] Likewise, there are significant ranges in procedure times for other types of surgery as well. For example, surgery for endometriosis might range from 10 to 240 minutes, while a hysterectomy might range between 25 and 400 minutes.[236] And procedure

[234] *Id.* ¶ 8.
[235] Shushan A, Mohamed H, Magos AL. How long does laparoscopic surgery really take? Lessons learned from 1000 operative laparoscopies. Hum Reprod. 1999 Jan;14(1):39-43. doi: 10.1093/humrep/14.1.39. PMID: 10374091.
[236] *Id.*

times are generally similar between robotic and non-robotic laparoscopic procedures. For example, one study determined that total operating time "did not differ significantly" between robotic assisted and non-robotic assisted laparoscopic cholecystectomies.[237]

218. Further studies have outlined the significant range in operative time from patient to patient even in the same type of surgeries. One study examining laparoscopic colon surgeries found ranges between 50 and 300 minutes for Ileocecal colectomies, between 62 and 330 minutes for sigmoid colectomies, and between 130 and 590 minutes for total abdominal colectomies.[238] This significant range in the length of surgical time even between patients undergoing the same type of surgery further illustrates the lack of uniformity in the time that instruments are used during surgery.

219. Instruments used in surgeries can also be used in varying ways. Some instruments might be used for complex anastomosis (sewing or suturing), while other instruments might be used to grasp or hold tissue in a single position during the surgery.[239] Instruments might be used for short periods of intense usage that place great strain on the instrument, or they might be used for long periods with minimal strain placed on the instrument.

220. All of these variables show why there is a variance in frequency of repairs for traditional laparoscopic instruments—they require repair service at different rates depending on how they are used in surgery. As discussed above, Bob Overmars testified that traditional laparoscopic instruments may be used "dozens to hundreds" of times before being repaired, and

[237] Ruurda, Jelle P., et al. "Analysis of Procedure Time in Robot-Assisted Surgery: Comparative Study in Laparoscopic Cholecystectomy." *Computer Aided Surgery*, vol. 8, no. 1, 2003, pp. 24–29., doi:10.3109/10929080309146099

[238] Scheer, Adena, et al. "Laparoscopic Colon Surgery: Does Operative Time Matter?" *Diseases of the Colon & Rectum*, vol. 52, no. 10, 2009, pp. 1746–1752., doi:10.1007/dcr.0b013e3181b55616.

[239] McGrogan depo. (*Rebotix*) tr., 26:8-25.

that the functional characteristics of the instrument, such as "lack of grip of the instrument jaws," and "dull scissors" determines when they require repair.[240] Therefore, an instrument that is heavily used during a few long and intense surgeries will experience more significant wear than an instrument that is used in a much larger number of shorter and less intense surgeries.

221. EndoWrists are similarly used for different amounts of time during surgery—they can be used for a few seconds, a few minutes, or for multiple hours.[241] They are also used in different ways during surgery.[242]

222. A system designed to accurately track the actual wear that an EndoWrist experiences in surgery would consider, at a minimum, both the length of time that instrument has been used, and the complexity of the tasks the instrument performed, in addition to potentially other factors. Intuitive has acknowledged the obvious point that to accurately reflect the wear that an instrument has experienced, one would want to take into account at least the length of time that an instrument was used in surgery and the complexity of the tasks performed in that surgery.[243]

2. The use counter does not account for the length of time or complexity for which an instrument is used during surgery.

223. The use counter decrements a single life as soon as the EndoWrist is manipulated from the surgeon console regardless of the time an instrument has been used or the complexity of the instrument's use during surgery. It follows that the remaining use count does not in any way indicate how or for how long the EndoWrist was used in prior surgeries.

[240] Overmars depo. (*Rebotix*) tr., 98:10-16.
[241] McGrogan depo. (*Rebotix*) tr., 24:11-17.
[242] *Id*. at 26:8-25.
[243] *Id*. at 32:9-22.

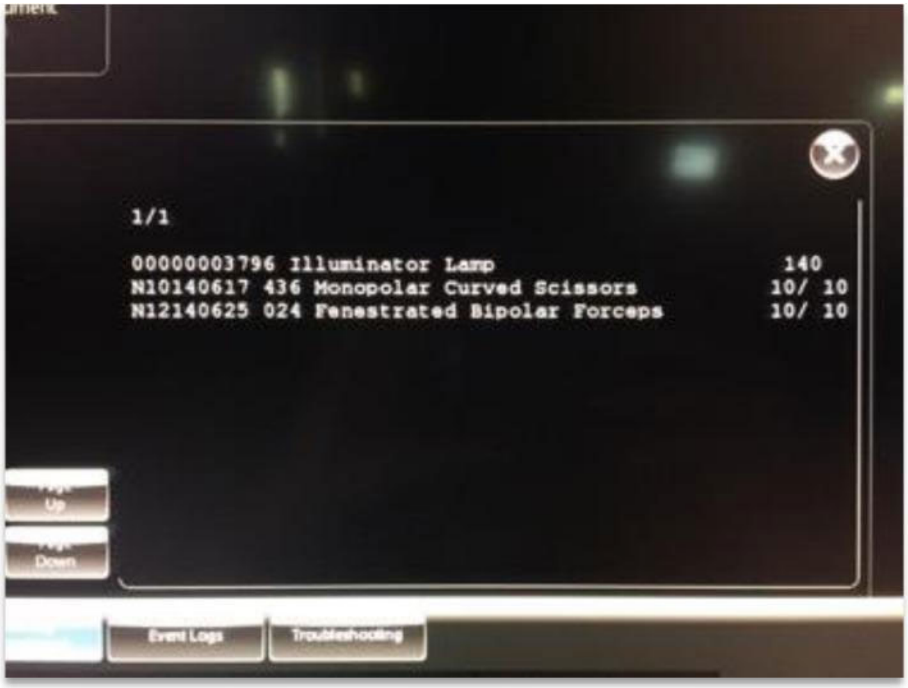


Image from Da Vinci Vision Cart

224. As shown above, the only information that the use counter displays is the serial number, the original number of uses and the remaining number of uses. Once an EndoWrist instrument is attached to the da Vinci robot and used in surgery in any way, a life is subtracted from the use counter.[244] That is the case whether an instrument is used for ten seconds or two hours inside a patient's body.[245]

225. That the dramatic time differences in surgeries discussed in the previous section—ranging between 10 minutes and almost 10 hours—are completely disregarded by Intuitive's use counter is confirmed by Anthony McGrogan, an Intuitive Vice President of product design. At his deposition, McGrogan was asked about two hypothetical EndoWrist instruments: (1) one

[244] McGrogan depo.(*Rebotix*) tr., 17:13 –18:6.
[245] *Id*.

instrument was used for one minute in each of its ten uses before the use counter read zero and (2) another was used for one hour for each of its ten uses before the use counter read zero. Even though one instrument was only used for ten minutes in surgery and the other was used for ten hours, Intuitive requires each of those instruments to be thrown away because the use counter in both has been decremented to zero:

> Page 24
> Q. Now, let's assume that there is one instrument that's used ten times for about an hour
> Page 25
> per surgery. Okay? Are you with me?
> A. Yep.
> Q. That instrument, according to Intuitive, is safe to be used for ten uses; right?
> A. Yes.
> Q. After those ten uses are up, Intuitive would tell the hospital you need to throw this instrument away; right?
> A. Right.
> Q. Now, let's take another instrument, same instrument. Let's use a cold grasper. It's used for one minute during surgery at different times.
> A. M-hm.
> Q. Was that a "yes"?
> A. Yes.
> Q. Intuitive would also tell the hospital to throw that instrument away after ten uses; right?
> A. Yes.
> Q. So the first instrument would have been used actually in surgery for ten hours; right?
> A. M-hm.
> Q. "Yes"?
> A. The total surgical time is, I believe, ten -- yes, ten hours.

> Page 26
> Q. The second instrument would have been used
> in surgery for ten minutes; right?
> A. Yes.
> Q. Intuitive would tell hospitals that each
> one of those instruments needs to be thrown away;
> right?
> A. That's true.[246]

226. Further, the complexity of different surgical procedures and what each EndoWrist instrument is used for is not reflected in the uses remaining on the use counter. McGrogan confirmed that hospitals are not required to distinguish between simple and complex procedures.[247] For example, a grasper could be used to grasp tissue a single time during a surgery, or dozens of times. In either case, the use counter will decrement a single life from the instrument, failing altogether to reflect the difference in actual usage between these two instruments.

227. Intuitive's purported inclusion of the use counter is to ensure patient safety, but the use counter itself fails to accurately take into account the key metrics of instrument wear. Measuring the life of an instrument should take into account both the time an instrument has been used and the complexity of the procedures for which the instrument was used—as acknowledged by Mr. McGrogan.

> Q. Well, one way that Intuitive could measure
> the life left in an instrument would be to measure
> the instrument based on the time that it's been used
> in surgery; right?
> A. I think we talked that time is not a good
> metric for measuring wear and tear.
> Q. Well, the time takes into account how --
> how long an instrument has been used in a given

[246] *Id.* at 24:24 – 26:7.
[247] *Id.* at 28:21-25.

procedure; right?
A. That's all it takes into account.
Q. Another thing that you might want to take into account would be the complexity of what the instrument is being used for right?
A. That's right.
MR. RUBY: Object to the form of the question. But it's been answered.
///

Page 33

BY MR. ERWIG:
Q. I'm sorry. I didn't get your answer.
A. I said yes.[248]

Page 33

Q. Now, a decrementing of the life on a use counter, that doesn't take into account either the time that the instrument has been used in surgery or the complexity of what the instrument did during the surgery; right?
A. That's right, as far as I know. Again, I don't know the details of the algorithm. But, generally speaking, if you use it in surgery, it's going to get decremented.
Q. That's the same whether it's been used for ten simple short procedures or ten --
A. Yes --
Q. -- complex, long procedures; right?
A. Yes, yes.[249]

228. Accordingly, the Intuitive use counter does not provide the surgeon with any practical or relevant information about the instrument's actual usage, such as time of use, how the instrument was used, number of particular movements, type of movements, types of procedures,

[248] *Id.* at 32:9–33:3.
[249] *Id.* at 33:4-17

forces experienced, whether an instrument malfunctioned, or whether it was misused or abused.[250] Nor does it account for extreme use cases that might require replacement after a single use.[251]

229. A result of the Intuitive EndoWrist use counter's failure to accurately track an instrument's useful life is that EndoWrists can and do fail prior to the use counter expiring. By the same token, EndoWrists that reach the maximum number of uses may still be capable of safe use beyond that number. This has been borne out in the actual use of EndoWrists--hospitals encounter EndoWrist failures before the use counter has expired, and also have EndoWrists with one remaining use on the use counter that show no signs of wear or failure.[252]

230. Intuitive measures and stores the electrical current of the motors that operate the cable and pulley systems of the EndoWrists during a procedure, which in turn is proportional to the motor torque.[253] Based on this data, Intuitive has the ability to monitor how long an EndoWrist was actually used during surgery as well as the types of forces and movements that the EndoWrist experienced during each surgery.[254] In fact, Intuitive uses this data to identify root causes for EndoWrist failures.[255] Nonetheless, despite having data available that could be used to more accurately determine wear and tear, Intuitive chooses to ignore this information in favor of its simplistic and arbitrary use counter.[256]

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[250] Mahal Report ¶ 65; Rubach Report ¶¶ 30-33.
[251] Mahal Report ¶ 66; Rubach Report ¶¶ 31-32.
[252] Harrich depo. ((*Rebotix*) tr., 41:12-17, 59:10-24, 165 12:20, Donovan depo. (*Rebotix*) tr., 34:20-25, 145:21-146:6.
[253] Duque 30(b)(6) depo. tr., 13:22-15:15.
[254] *Id.*
[255] *Id.* at 16:6-17:14.
[256] *Id.* at 18:25-19:10.

231. Traditional laparoscopic instruments do not have use counters.[257] Instead, the instruments are routinely inspected, repaired, and continue to be used.[258] And if an instrument cannot be repaired, that instrument is discarded and no longer used in surgeries.

232. Hospitals measure wear on instruments by assessing whether they are performing the required function in surgery. Evidence in this litigation shows that EndoWrists frequently performed no differently by the end of their tenth use than they had on their first use. For example:

> Q. You stated that you believed EndoWrists had
> additional lives on them before you had to dispose of
> them when they reached their maximum use restrictions;
> is that right?
> A. That's correct.
> Q. Why did you believe that EndoWrists had
> additional lives on them?
> A. Well, on the end of the tenth life, it wasn't
> working any different than it had been on the first
> life. There was no complaints by the physicians. If
> there were any, we'd take the instrument out of
> service or send it back in to Intuitive for repair if
> it still had lives left on it.
> So if it's a grasper, it's a grasper. Is it
> grabbing the tissue like you think it should? As the
> physician says, it's feeling that tactile touch. You
> can't actually feel the touch, but on a console.
> Page 36
> But it's grabbing the tissue. They're liking
> what they're seeing. They're liking what they're
> feeling. So the instrument can still continue to be
> used.
> Q. Is that how you determine whether a
> traditional laparoscopic device should continue to be
> used as well?

[257] Mahal Report ¶ 64; Rubach Report ¶¶ 28-30.
[258] Donovan depo. (*Rebotix*) tr., 40:9-13, Harrich depo. (*Rebotix*) tr., 45:10-20.

8 A. Yes, the functionality of it.[259]

This serves as further evidence of how Intuitive's use counter fails to measure actual instrument wear.

B. The use counter does not take into account mishandling or misuse.

233. Misuse, mishandling, or improper cleaning can occur at any time, including before an instrument's use counter reaches zero. For example, during my visit to the Rebotix facility, I saw numerous instruments that had experienced a failure prior to their use counter expiring. Those failures included snapped tool ends, fully cut cables, frayed wires, and broken instrument shafts.

234. The EndoWrist use counter does not take these failures into account or track whether those failures have occurred.[260] An instrument can have five or six remaining uses, but misuse can cause broken scissors, bent graspers, or broken cables. The only way to accurately determine whether an instrument has been misused or mishandled is through visual inspection and testing. The use counter does not in any way ensure that an instrument has not been subject to mishandling or misuse.

1. Instruments frequently experience failures due to mishandling or misuse.

235. Intuitive's RMA data show that instruments frequently experience failures prior to the usage counter expiring that are caused by misuse, mishandling, or improper cleaning during reprocessing.[261] For example:

[259] Harrich depo. (*Rebotix*) tr., 35:9 – 36:8
[260] Mahal Report ¶¶ 65-66; Rubach Report ¶¶ 31-33.
[261] Intuitive-00695006.

a) Cable breaks:

236. Cable break during procedure, causing a "segment of the conductor wire sticking out from the yaw pulley" and the broken piece to go missing "as a result of the breakage." The failure was caused by mishandling/misuse, such as excess force applied to distal end of the instrument.[262]

237. The forceps were found to have a "frayed grip cable at the distal idler pulley." The frayed cable strands "stuck out at the wrist" of the instrument. This failure is "most commonly caused by mishandling/misuse, such as excessive contact with abrasive or hard surfaces during transport or reprocessing."[263]

238. The bipolar forceps were "found to have a broken conductor wire at the yaw pulley." The instrument was also "found to have damage at the conductor wire's insulation" and "failed the electrical continuity test." This failure is "commonly caused by mishandling/misuse, such as collision of the instrument with a sharp object."[264]

b) Grip Failure:

239. Tips of instrument grips were severely bent during the procedure, causing the mouth of the forceps to be "out of alignment." This failure was "caused by mishandling/misuse, such as excess force applied to the instrument jaws."[265]

240. Tips of instrument grips were broken. "This failure is most commonly caused by mishandling/misuse, such as excess force applied to the instrument grips."[266]

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[262] Intuitive-00695006, Tab 1, Row 39574.
[263] *Id.* at Tab 1, Row 140045.
[264] *Id.* at Tab 1, Row 96870.
[265] *Id.* at Tab 1, Row 41874.
[266] *Id.* at Tab 1, Row 71189.

241. The instrument was found to have a "severely bent grip." This failure is "most commonly caused by mishandling/misuse, such as excess force applied to the instrument jaws." The instrument had 3 uses remaining.[267]

c) Scissor Failure:

242. One of the scissor blades on the EndoWrist was indented, preventing the blades from closing. The instrument had 10 uses left. This failure is "most commonly caused by mishandling/misuse."[268]

243. The blade edges on the Potts scissors were indented, preventing the blades from closing. The instrument had 2 uses left. This failure is "most commonly caused by mishandling/misuse."[269]

244. The monopolar curved scissors were found to have blade damage in the form of mechanical indentations on one of the blade edges. This prevented the "blades from closing" and is "most commonly caused by mishandling/misuse." The instrument has 3 uses remaining.[270]

d) Unintuitive motion:

245. The needle driver was "found to have an input disk broken" and "completely detached from the base of the housing." The most common cause of this failure is "improper cleaning during reprocessing" such as "prolonged exposure of instrument to harsh cleaning agents." As a result, "the instrument was non-intuitive." The instrument had 3 uses remaining.[271]

[267] Intuitive-00695006, Tab 1, Row 47663.
[268] *Id.* at Tab 1, Row 77102.
[269] *Id.* at Tab 1, Row 127428.
[270] *Id.* at Row 42737.
[271] *Id.* at Tab 1, Row 70097.

246. The prograsp forceps were "found to have contamination at the clamping pulley, causing the grip movement to be stiff." This didn't allow the forcep tips to open enough for "proper tissue handling." The surgical tech replaced the instrument with another one in order for the procedure to continue. The known common cause of this failure is "due to mishandling/misuse." The instrument had 3 uses remaining.[272]

247. The monopolar curved scissors were "found to have the tube extension mating keys damaged." This failure is commonly caused by "hyper-rotating the proximal clevis relative to the tube extension." Moreover, "signs of corrosion were found on the instrument bearings," most commonly caused by "improper cleaning during reprocessing." The instrument had 3 uses remaining.[273]

248. That misuse, mishandling, or improper cleaning can occur at any time, including before an instrument's use counter reaches zero. For example, during my visit to the Rebotix facility, I saw numerous instruments that had experienced a failure prior to their use counter expiring. Those failures included snapped tool ends, fully cut cables, and broken instrument shafts.

2. <u>None of those failures are reflected in the use counter and may occur at any time.</u>

249. An instrument's use counter does not take these failures into account, or track whether those failures have occurred. An instrument can have five or six remaining uses, but misuse can cause broken scissors, bent graspers, or broken cables. The only way to accurately determine whether an instrument has been misused or mishandled is through visual inspection or

[272] Intuitive-00695006, Tab 1, Row 57332.
[273] *Id.* at Tab 1, Row 76027.

testing. The use counter in no way detects that an instrument has been mishandled or misused, and does not prevent it from being damaged from such.

C. <u>**Intuitive's life testing is designed to validate an arbitrarily set use limit set by marketing, rather than to establish the failure point of an instrument.**</u>

1. <u>To accurately establish a use limit or failure point, tests would need to actually test instruments to failure.</u>

250. In my experience, studying the failures experienced by mechanical components and medical instruments, testing instruments to failure and observing at which points those failures occur, all help to establish the potential range of life for an instrument. Establishing and identifying the potential failure modes accurately is extremely important.[274] In the absence of this data and insight, one's ability to understand the EndoWrist system performance (especially the potential life) is limited. Intuitive primarily utilizes returned EndoWrists that are shown in the RMA log for failure analysis and root cause analysis. This data is useful, but many EndoWrists may never appear in the RMA data. For example, since there is no potential monetary credit for an EndoWrist with zero (0) lives remaining, many of these EndoWrists will be discarded rather than shipped to Intuitive. Some incentive is needed to get these EndoWrists for evaluation. As an example, in a sample of ten tested instruments, testing each to failure would involve setting certain failure conditions (such as breaks in instrument cables or dulled scissors) and observing at which point each of the instruments experiences a failure. In that ten-instrument sample, one instrument might fail at use 50, and nine others might fail after use 200.

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[274] *See, e.g.,* "Engineering Failure Analysis, Fatigue & Mechanical Tests: DNV Labs." *DNV*, www.dnv.com/oilgas/laboratories-test-sites/engineering-failure-analysis-fatigue-tests-and-mechanical-tests-dnvgl-labs-hovik.html., and "Failure Analysis Testing: Engineering Failure Analysis |." *Stress Engineering Services, Inc*, 14 Feb. 2020, www.stress.com/capabilities/materials-engineering/failure-analysis/.

251. By contrast, halting tests after a certain number of uses produces skewed results. In the above example, if testing for the nine other instruments were arbitrarily halted at use 60, the results of the testing would indicate that the instruments had a lower acceptable life. Testing to failure produces a more accurate and insightful statistical analysis of instrument failures, because it actually establishes the range of failure conditions and the useful life of an instrument.

2. <u>Intuitive testing is designed to validate target lives set by marketing and does not accurately assess the failure point for the instrument.</u>

252. Intuitive life testing does not accurately assess the useful life of an instrument. Instead of attempting to establish the maximum number of lives that an instrument can be safely used, Intuitive's testing aims to statistically validate a preset target limit.

253. The initial targets for the Intuitive EndoWrist use counter are set by marketing, and help to support the Intuitive published revenue model.

> Page 35
> Q. Now, when Intuitive is first considering
> what it's going to be setting the lives at,
> marketing is involved in that process; right?
> A. Marketing is involved to the extent that
> they set goals for engineering.
> Q. For example, marketing might set a goal of
> ten lives for an instrument; right?
> A. That's an example, yes.
> Q. And then engineering would try to design an
> instrument that would meet that ten-life goal;
> right?
> A. Yes.[275]
>
> Q. But when a new instrument is being
> developed for a customer, marketing is setting the

[275] McGrogan depo. (*Rebotix*) tr., 35:9-20

> target for that instrument before there's any
> testing that's conducted; right?...
> THE WITNESS: Marketing sets a goal for
> reposable instruments.
> BY MR. ERWIG:
> Q. Then engineering designs and tests an
> instrument to try to achieve that goal; right?
> A. That's right.[276]

254. And the testing performed on an instrument to establish the number of lives on the use counter takes place only after those initial targets have been set by marketing and provided to engineering.

> Q. Now, for formal life testing, formal life
> testing is performed after there's been a particular
> target set by marketing; right?
> A. Typically, yes, formal life testing.
> Q. That's ultimately what's used when
> Intuitive sets the life counter; right?
> A. Yes.[277]

255. Once those targets are set, Intuitive tests to the targets to be very safe with a high reliability and high confidence. Intuitive's Weibull Design of Reliability aims to test a sample of instruments to confirm that instruments will reliably meet a pre-set life target.[278] Intuitive deliberately chooses to stop its life testing protocols shortly after the instruments being tested pass the target number of lives. For example, during Intuitive's life testing for extended life instruments, it prematurely halted testing instead of testing all instruments to failure.[279] For Intuitive's initial

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[276] *Id.* at 64:5-19 (objection omitted)
[277] *Id.* at 65:19-25.
[278] *See, e.g.,* Intuitive-00542459 – Intuitive-00542461.
[279] Intuitive-00642553.

life testing of many of its highest-usage Xi EndoWrists, it stopped testing once it statistically justified 10 uses even though none of the instruments experienced a failure.[280]

256. The result of this target-based testing approach is that engineers test with those targets in mind, and aim to establish reliability for those particular targets. Rather than establishing where failures naturally occur by testing each instrument to failure, the testing process is stopped after justifying the target number of instrument lives.

Page 47
Q. Now, telling the lab to stop testing
instruments at a certain point, that could involve
telling the lab to stop testing instruments once
they've reached 17 uses, for example; right?
A. Yes.
Q. Another option would be not to set any stop
point for the instruments; right?
A. Yes.
Q. In other words, continuing to test the
instruments until they exhibit failure conditions;
right?
A. Yes.
Q. In this particular testing, the instruments
were stopped at a certain point; right?
A. Yes.
Q. The testing was not performed all the way
through to failure; right?
A. Yes.[281]

Page 45
Q. Sure. Marketing might set a target for 15
lives; right?

[280] Duque 30(b)(6) depo. tr., 63:11-64:18; Duque 30(b)(1) depo. tr., 115:19-117:15; Duque Ex. 268 (Intutiive-02066979) at 02067029 (stopping testing at 13 life cycles with no failures), 02067033 (stopping testing at 15 life cycles with no failures), 02067034 (stopping testing at 15 life cycles with no failures), 02067038 (stopping testing at 13 life cycles with no failures), 02067039 (stopping testing at 10 life cycles with no failures).

[281] McGrogan depo. (*Rebotix*) tr., 47:3-20

A. Sure. Yes.
Q. If instruments were tested to failure, then
Page 46
each instrument would be tested until it experienced
a failure condition; right?
A. Yes.
Q. And that could happen at 20 uses; right?
A. Yes.
Q. It could happen at 25 uses?
A. Yes.
Q. It could happen maybe even at 30 uses?
A. Yes.[282]

257. Instruments have passed Intuitive's life testing metrics for higher lives than were actually implemented.

Page 59
Q. Well, there's certainly been instances
where the instrument being tested passed more lives
than were actually implemented; right?
A. Yes.
Q. Now, the instrument could have been set at
a higher number of lives; right?
A. Yes.
MR. RUBY: Object to the form of the
question. The witness has answered.[283]

Page 62
Q. There's certainly some instances where the
number of lives implemented is different from the
number of lives proven; right?
A. Yes.
Q. And the number of lives implemented, those
are less than the lives proven; right?

[282] *Id.* at 45:22 – 46:9.
[283] *Id.* at 59:9-17.

> A. Yes, in some cases.[284]

258. Those higher life counts were not implemented because marketing's decision to set the use counter to particular values is driven by maximizing Intuitive's revenue and profits. As early as 1995, in Intuitive's original business plan, it expected to use instruments as a "major part of [its] recurring revenue."[285] Its early 10-K's similarly indicated its intention to extract per-procedure pricing.[286] And Intuitive's representatives confirmed that use counters with lower life counts would generate more revenue for Intuitive.

> Page 143
> Q Well, let's assume the same price. If you
> sell an instrument to a customer that has one use, the
> customer needs to buy more of those instruments than
> if an instrument has, let's say, five uses; right?
> A Yes. And if you set the same price for the
> one use and five use, then you would see more revenue,
> maybe not profit, but on one -- one instrument -- on a
> one-use instrument.
> Q And if the customer only had the option of
> buying that one-use instrument, it would be better
> from a revenue perspective to only design a one-use
> instrument instead of a five-use instrument; right?
> A Assuming constant demand and constant volume,
> from a purely revenue standpoint, not profit, then I
> think that's a true statement.[287]

[284] *Id.* at 62:10-16.

[285] Intuitive-00595682.

[286] *See* 2001 Intuitive 10-K at p. 6 ("In addition, the chip will not allow the instrument to be used for more than the prescribed number of procedures or hours so that its performance meets specifications during each procedure. In addition, we can sell the instrument for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure or per-hour basis."). It is telling that even though Intuitive acknowledged the ability to measure time of usage in 2001, it chose the least accurate method of per-use pricing.

[287] DeSantis depo. (*Rebotix*) tr., 143:6-20

259. Intuitive's decision not to re-evaluate the use counter on its Si instruments is a further example of revenue concerns, rather than safety, driving the number of uses that the use counter is set to.

> Page 173
> Q Now, in 2013, if Intuitive wanted to give
> hospitals the maximum possible number of uses out of
> every Si instrument, Intuitive could have tested the
> Si instruments and seen what the appropriate number of
> uses was as of that time; right?
> A That's -- that's one option, yes.
> Q Instead Intuitive left the life counter for
> the Si instruments at ten uses; right?
> A Intuitive was investing heavily in a better
> platform at that time, so we did not choose to invest
> in the Si instruments to do a life testing and roll
> out that program. Correct, we did not do that.
> Q And so Intuitive left the life counter of the
> Si instruments at ten uses and didn't try to increase
> it to 12, 13, or anything else; right?
> A Correct.[288]

260. Intuitive never attempted to extend the lives of Si EndoWrists, despite the Si data showing that they failed at a significantly lower rate than Xi EndoWrists.[289]

261. And even when Intuitive considered an extended lives program for its Xi EndoWrists, revenue considerations were driving its analysis. For example, Intuitive conducted a worst case and best case financial impact assessment on the extension of reprocessing cycles for instruments.[290] However, this document does not include a best and worst case safety assessment.

[288] *Id.* at 173:2-17

[289] Duque 30(b)(1) depo. tr., 80:8-12, 81:5-24, 82:3-19 ; Duque Ex. 247 (Intuitive-009657510) at 00967511, 00967513.

[290] Intuitive-00624804.

D. <u>The use counter fails to independently verify the condition of the instrument. Hospital technicians must do an inspection to ensure that the instrument is safe.</u>

262. The use counter itself does not provide any information about whether an instrument is safe to be used. The use counter does not indicate whether wires are frayed, whether scissors are dulled or broken, or whether there are other errors with the device. The only data of any value provided by the use counter is how many times the instrument has been "used," i.e., attached to the robot and initiated some movement in following mode.[291] No matter how much time or how severely the use for an EndoWrist in a particular surgery, a single use occurs each time the EndoWrist is mounted to the da Vinci robot and put into tracking mode. Sometimes multiple EndoWrist swaps occur at various points within the same surgical operation. In this case, multiple lives may be decremented for the single patient and single procedure. Likewise, an EndoWrist may receive minimal use over a short amount of time in a procedure, and a single use is still decremented.

263. Rather than relying on the use counter, hospitals examine EndoWrists before surgery to determine whether they are safe for use.[292] When hospital technicians recognize issues with an EndoWrist, it will not be used in surgery. However, there is no way around a lightly used EndoWrist with no damage and minimal wear once the use counter is fully decremented. It becomes part of the waste stream (or a possible wall decoration).

264. Numerous instruments at the Rebotix facility that were received from hospitals and were ultimately deemed "Unsuitable for Repair" had remaining uses on the use counter. For

[291] Mahal Report ¶¶ 65, 66; Rubach Report ¶¶ 30-32.
[292] Harrich depo. (*Rebotix*) tr., 40:12-25, Donovan depo. (*Rebotix*) tr., 33:23-34:9, 35:16-21.

example, the instruments I examined with broken cables all had remaining uses. The use counter would not prevent at least an initial attempt to use those instruments in surgery. Either an initial inspection identifies the issue or the procedure starts and then the surgeon determines that the instrument is not performing as needed and has to replace the malfunctioning EndoWrist.

XI. THE SIMILARITIES BETWEEN THE ICONOCARE PROCESS THAT FDA APPROVED AND THE REBOTIX PROCESS CONFIRMS MY ANALYSIS OF THE REBOTIX PROCESS

265. On September 30, 2022, the FDA informed Iconocare Health that it had "reviewed your Section 510(k) premarket notification of intent to market the [8mm Monopolar Curved Scissors] device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices[.]"[293] The 510(k) summary, attached on November 15, 2022, lists a number of "Legally Marketed Predicted Devices" manufactured by Intuitive,[294] and concluded that "[t]he design, materials, and intended use of the 8mm Monopolar Curved Scissor Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the subject device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, or method of operation."[295]

266. FDA ultimately concluded that "[t]he [Iconocare] performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended."[296] FDA also discussed the Iconocare "risk analysis" and "[d]esign

[293] Exhibit 301 to Claiborne Deposition at p. 2.
[294] *Id.* at p. 5.
[295] *Id.* at pp. 5-6.
[296] *Id.* at p. 6.

verification and validation testing," which included "Biocompatibility," "Validation of Reprocessing," "Functional Performance Testing," and "Electrical Safety Testing."[297]

267. I do not purport to be an expert on FDA procedures, however, both the FDA clearance of used EndoWrists that undergo the Iconocare procedure and my review of the FDA-Iconocare files, further buttress my conclusion that Rebotix process and similar processes provide for robust repair of EndoWrist instruments. From my mechanical engineering and medical device/equipment perspective, the Iconocare EndoWrist repair process will allow many of those instruments to operate safely and effectively after the initial number of uses specified by Intuitive.

A. <u>The Iconocare process is similar to the Rebotix process.</u>

268. The visual inspection procedure utilized for the Rebotix process and Iconocare process are virtually identical, with the narrow exception that [redacted]

[297] *Id.*

Rebotix:[298]

5.2. Visual Inspection:

5.2.1. Verify the labeling (Name, REF, LOT, VER) on the instrument housing are clearly legible.
5.2.2. Verify there are no cracks or other damage to the instrument housing.
5.2.3. Verify that there are no missing tabs or other damage to the manipulation wheels on the bottom of the Instrument.
5.2.4. Verify that the manipulation wheels move freely in each direction throughout its full intended range of motion.
5.2.5. Verify the cautery pin/s are intact and not bent (Electrosurgical *EndoWrist® Models Only)*.
5.2.6. Verify there are no cracks or other damage to the instrument shaft.
5.2.7. Inspect the instrument tool end under magnification for:
5.2.7.1. Broken or frayed manipulation cables.
5.2.7.2. Broken or damaged Electrocautery cables (Electrosurgical *EndoWrist® Models Only)*.
5.2.7.3. Tool end/jaw alignment.
5.2.7.4. Tool functionality (Scissor cutting efficiency, grasper alignment)
5.2.8. Record the Visual Inspection results on the Form.

[redacted]

269. [redacted]

[298] REBOTIX162404 at REBOTIX162413.
[299] [redacted].

[redacted]

270. [redacted],"[300] "[redacted],"[301] "[redacted]"[302] and notably, "[redacted]."[303] Contrary to Dr. [redacted],[304] [redacted]

Rebotix:

6.4.1. Cable Tension Adjustments:

6.4.1.1. Place Wrist in the Tension Fixture. Align the 4 manipulation wheels so that their locator tabs fit into the female receptacles on the fixture. Engage the clamp to prevent the Wrist from coming out of the fixture. Engage the shaft clamp to prevent shaft rotation.

6.4.1.2. Use the Tool End Tension Fixture to lock the tool end of the wrist in its neutral position. Neutral position is achieved when the tool end is straight, and any jaws are closed. This is achieved by turning the screw clamp onto the wrist and adjusting the jaw slides.

6.4.1.3. Using the hex screwdriver loosen the screws of the top spool of the Pitch Manipulation Wheel Assembly. Verify the cable is wrapped around the spool correctly, fitting into the defined grooves. Verify the cable runs through the correct pulleys in the pulley assemblies. Using the screwdriver turn the spool to apply tension to the cable. Only enough tension to remove the slack from the cable is required. Do not over tension the cable as this could create problems during use.

6.4.1.4. Repeat the process in 6.4.3 for the bottom spool.

6.4.1.5. Repeat the previous steps for the top and bottom spools of both of the Jaw Manipulation Wheel Assemblies.

6.4.1.6. Remove the Wrist from the Tension Fixture.

6.4.1.7. Place the Wheel Locator Fixture onto the Manipulation Wheels so that the wheel tabs fit into the grooves on the fixture.

6.4.1.8. Verify that the Tool End is in a neutral position and that when you try to manipulate it by hand that it has little to no movement.

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[300] *Compare* REBOTIX162413-17 [redacted].

[301] *Compare* REBOTIX162422 [redacted].

[302] *Compare* REBOTIX162422 [redacted].

[303] *Compare* REBOTIX162421-22 [redacted]

[304] Howe 2-24-23 depo. tr., 61:23-62:5 ("Q: As you sit here today, can you identify any deficiencies in the Iconocare process? A: . . . And I don't believe I cite any. In the context of comparing the Rebotix Restore process to the Iconocare process, I don't find any deficiencies that are cited.").

[redacted]

271. [redacted]. The Iconocare process that the FDA approved and that Dr. Howe seems to accept (or at least offers no direct criticism for) is effectively identical in all critical respects, including on numerous issues that Dr. Howe criticizes elsewhere in his report. These similarities, FDA's approval of the similar process, and Dr. Howe's lack of criticism of the similar Iconocare process provide further support for my opinions regarding the Rebotix process.

B. Iconocare risk management and life testing are similar to Rebotix risk management and life testing – Dr. Howe never attempts to identify any "significant" differences.

272. Dr. Howe contends that there are "significant differences between the risk management and life testing data Rebotix had access to in connection with the Rebotix Process and the risk management and life data submitted to the FDA for the Iconocare Process."[305]

273. While Dr. Howe's analysis may identify "differences" between the documentation for the two processes, nowhere does Dr. Howe attempt to explain why any such difference are in any way significant.[306] In fact, as to the subjects apparently addressed by the vague descriptions in the Howe Hospital Report, Rebotix performed ample testing and had robust risk management processes.

274. Regarding testing,[307] Dr. Howe never actually discusses the Iconocare life testing protocol and procedure,[308] and does not attempt to make any comparison of that protocol and procedure to the Rebotix life testing. As I discussed at ¶¶ 134-136 of this Report, the Rebotix life testing is robust and accurately reflects wear and tear under actual surgical conditions.

275. For other testing (including biocompatibility), as described above, Rebotix documented the original specifications and developed its repair process and employed third party testing laboratories to verify that its repaired EndoWrists complied with all applicable safety standards. Rebotix sent its repaired EndoWrists to SGS for electrical safety testing, and to IMR

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[305] Howe Hospital Report ¶ 153.

[306] *See* Howe Hospital Report ¶¶ 153-157 (generally discussing documentation without explanation as to what is "significant" about specific documentation).

[307] Howe Hospital Report ¶¶ 154-57.

[308] *See id.* (despite a section heading including "Life Testing Data," never actually discussing details of Iconocare's life testing, such as number of actuations or the life test protocol)

Test labs for materials testing. And Rebotix then had its entire service process evaluated by DQS-Med to confirm that it complied with all applicable safety standards.

C. Dr. Howe's attempts to identify "differences" between the Iconocare and Rebotix processes is unavailing – the identified "differences" are exaggerated or immaterial.

276. Dr. Howe first argues that the "[t]he Iconocare Process and Rebotix Process use different methods for altering the use counter in the instrument."[309] As an initial matter, as to SIS, it had a similar process to the Iconocare chip replacement process available to it from Restore.[310]

277. Dr. Howe criticizes the Rebotix chip update process for including "soldering and desoldering," "applying a conformal coating," and "drilling a hole."[311] Dr. Howe provides no evidence that any of these operations have ever caused any problems in a Rebotix chip update procedure, and as I discuss above in this Report, the Rebotix procedures for these operations are robust and well-documented. Any reasonably trained technician should be able to perform these simple steps of the Rebotix process without incident.

278. Dr. Howe also discusses the cleaning processes employed by Iconocare.[312] As I explain in detail elsewhere in this Report, Dr. Howe mischaracterizes the cleaning steps of the Rebotix process, which require cleaning after steps that generate debris as well as ultrasonic cleaning. Accordingly, Dr. Howe's comparison is not to the actual Rebotix process.

[309] Howe Hospital Report ¶ 144.
[310] Posdal 30(b)(1) depo. tr., 40:19-24; K. Johnson 30(b)(1) depo. tr., 45:13-25.
[311] Howe Hospital Report ¶ 146.
[312] Howe Hospital Report ¶¶ 147-148.

XII. AS LONG AS A SUITABLE INSPECTION AND REPAIR PROCESS IS PERFORMED, THERE IS NO ENGINEERING REASON THAT PREVENTS AN ENDOWRIST FROM MULTIPLE REPAIR CYCLES

279. Dr. Howe opines "that resetting an instrument's usage counter multiple times, as the Restore Process contemplated, has a significantly greater impact on instrument reliability and patient safety than resetting an instrument's usage counter just once under the Iconocare Process."[313] His sole engineering support for this proposition is "the Rebotix EndoWrist MDR Report."[314]

280. Regarding Dr. Howe's selective discussion of particular failures discussed in the Rebotix EndoWrist MDR Report, I analyzed this data above at § VII(B)(3) demonstrating that Dr. Howe's analysis was flawed based on the small sample size and his failure to consider misuse and recalls. Whereas Dr. Howe relies on a small, unrepresentative sample, my analysis of Intuitive's RMA data demonstrates that most of these failures are in fact caused by misuse that is not correlated with the number of uses. *See above* § X(B).

281. The only evidence that Dr. Howe cites for his conclusion that "[m]ore of these failures are observed in instruments that are later in their original ten-use life cycle than those at the beginning of that cycle" is a table at page 12 of the Rebotix EndoWrist MDR Report.[315] His report never discusses that this table only includes information on 61 total failures, and that he selectively identified his relative percentages "with 3 or fewer lives remaining" and "with 7 or

[313] Howe Hospital Report ¶ 161.

[314] *Compare* Howe Hospital Report ¶ 162 (referring back to "above" – without citation – for the proposition "that continued use of EndoWrists beyond their originally specified number of uses increases the risk of instrument failure") *with* Howe Hospital Report ¶ 113 (citing "the MDR Report" for the proposition "that instruments wear out and show increased failure rates with increased usage"); *see also* Howe Hospital Report ¶ 163 (citing only to ¶¶ 111-113 of the Howe Hospital Report, which in turn discuss data from "the Rebotix EndoWrist MDR Report").

[315] Howe Hospital Report ¶ 163 (referring to ¶ 113) and ¶ 113 (relying on "the MDR report" at REBOTIX090164).

fewer lives remaining" by adding together these failures and dividing them by the total number of failures.[316]

282. First, the data Dr. Howe used is simply too small of a sample and is too "noisy." As Dr. Howe admits, such a small sample is only adequate "[i]f it's a representative sample[.]"[317] Yet Dr. Howe also admits that "it's clear that this is a noisy process[.]"[318] I agree that this data is very noisy, for example, with a disproportionate number of "failures" at zero remaining uses and seven remaining uses, but identical numbers of failures at 2, 3 and 8 remaining uses, and at 4, 6, and 9 remaining uses.[319] In other words, that this small sample set is not representative is facially apparent from the data set. Dr. Howe admits as much, agreeing that from the single failure at 7 uses "it's clear that this is a noisy process," and that causes of failure, such as "the instruments not being recognized" with 0 remaining uses "can't be determined" and relatedly, that he "did not" make such a determination for his report.[320]

283. Second, Dr. Howe intentionally selected his sample sizes to increase the purported percentage with fewer lives remaining versus the percentage of failures with fewer lives remaining. To arrive at his conclusion that "most of the failures (53%) occurred in instruments with 3 or fewer lives remaining"[321] he necessarily included **four samples** (*i.e.*, 11+8+6+6/59[322]=0.525),[323] while

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[316] *Compare* Howe Hospital Report ¶¶ 113, 163 (never discussing the sample size) *with* Howe 2-24-23 depo. tr., 101:16-103:8) (admitting that "the grand total of [failures considered] is 61" and that his analysis consisted of "adding the number of failures together and then dividing them by the total number of failures").

[317] Howe 2-24-23 depo. tr., 100:25-101:5.

[318] *Id.* at 102:15-103:3.

[319] *Id.* at 101:16-103:22.

[320] *Id.* at 102:15-103:22.

[321] Howe Hospital Report ¶ 113.

[322] Dr. Howe's analysis appears to have ignored instruments with 10 use limits, which makes the denominator 59.

[323] REBOTIX019153 at REBOTIX090164.

to reach his conclusion that "only 19% of failures occurred in instruments with 7 or more lives remaining"[324] he necessarily included only **three samples** (*i.e.*, 1+6+4/59=0.186).

284. Third, Dr. Howe has included an outlier sample with significantly more failures (11) than the other samples in the "3 or fewer lives remaining" sample set, and an outlier sample with significantly fewer failures (1) than the other samples in the "7 or more lives remaining" sample set.[325] Particularly when combined with the different sizes of the sample sets, any conclusions that Dr. Howe draws from this small, unrepresentative and improper sample are scientifically and mathematically invalid under even the most basic statistical principals.

285. It is telling that Dr. Howe relies extensively on a statistically unrepresentative sample from Rebotix. Virtually everywhere else in his report he reflexively criticizes extremely robust Rebotix processes, such as the Rebotix life testing procedure.[326] In any event, Dr. Howe admits that Intuitive has available to it a very large and robust real-world RMA data set. This data set shows actual failures in the field and the associated EndoWrists returned to Intuitive and subsequently logged into the RMA database.[327] Dr. Howe states in his report that he believes the RMA data is more accurate than data available to Restore and Rebotix via MAUDE reports.[328] However, in reaching his conclusion that failure rates increased with more uses, Dr. Howe

[324] Howe Hospital Report ¶ 113.

[325] *Id.* at 102:15-103:22.

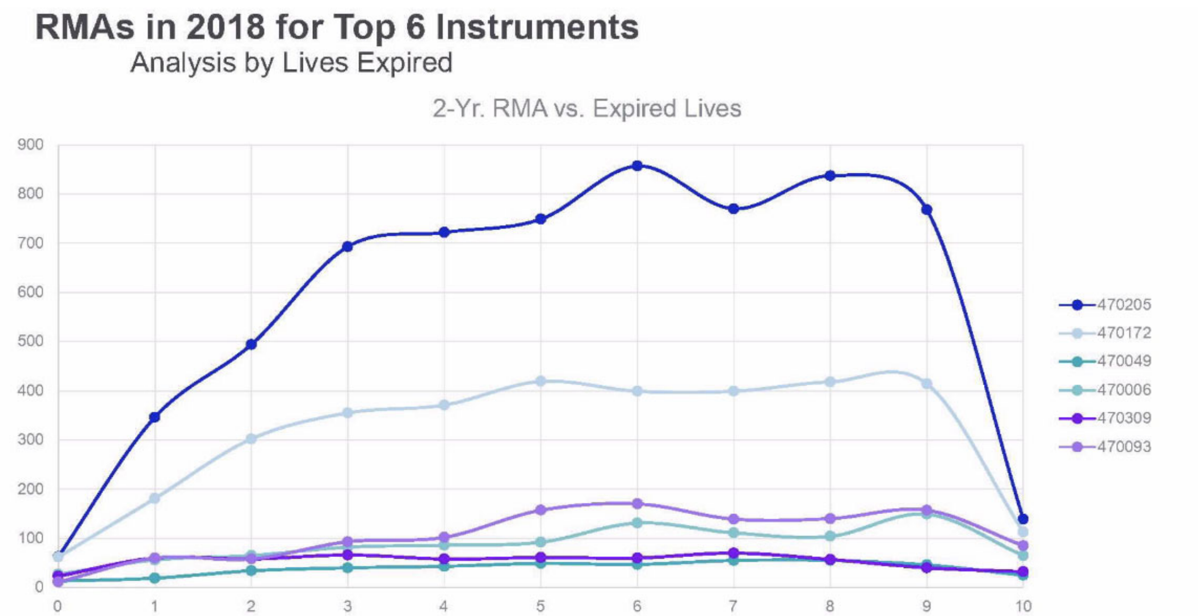
[326] *See above* at ¶¶ 130-156.

[327] Howe Hospital Report ¶ 74 ("Intuitive also confirms life testing data with RMA data trends, which originate from real-world use, rather than simulated surgical use, ... If RMA rates were to be misaligned with expected reliability predicted from life testing, then life testing would need to be modified to align with the reality observed through RMA rates.").

[328] *Id.* ¶ 76 ("Further, because Intuitive observes through its RMA process many instrument failures that occur as a result of wear and tear, . . . Intuitive thus has a large amount of data from real-world use. By contrast, there is minimal real-world use data from remanufactured instruments.").

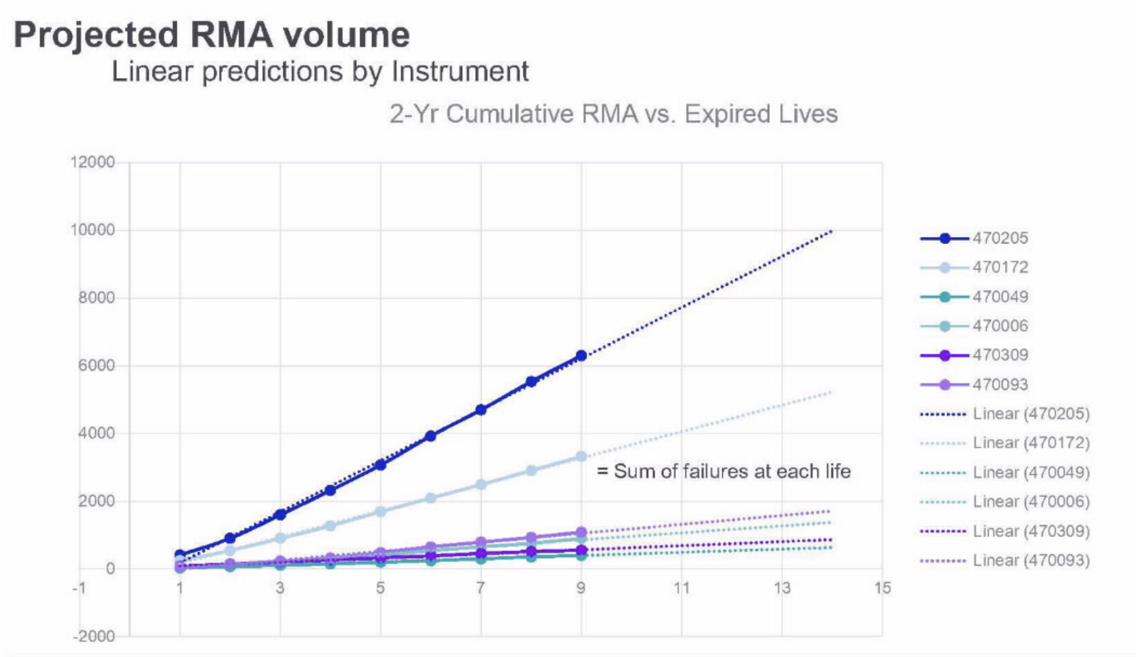
(reluctantly) admits that he never performed any calculations using the RMA data, and that he does not cite to the RMA data to support this conclusion.[329]

286. Intuitive performs analyses of RMA data as part of its standard quality control activities,[330] as well as for special projects such as the Extended Use program.[331] This data – which Dr. Howe appears to have ignored – conclusively demonstrates that at least within the first ten uses the failure rate for EndoWrists quickly level off and essentially remains constant. This RMA data clearly shows that it is no more likely that an EndoWrist will fail on any particular use over time.[332]



287. The cumulative RMA data also shows that the failure rate for EndoWrists quickly becomes linear.[333]

[329] Howe 2-24-23 Depo. Tr. at 90:3-97:15.
[330] *E.g.*, Intuitive-00967510; Intuitive-00970414.
[331] *E.g.*, Intuitive-00967614.
[332] Intuitive-00967614 at Intuitive-00967617-18.
[333] *Id.* at Intuitive-00967617-18.



288. Although this linear data pattern is limited to the 10 uses that Intuitive allows for nearly all of its instruments, the lack of an increase in failure rates with continued usage directly contradicts Dr. Howe's conclusions to the contrary. Further, this RMA data supports the conclusion that EndoWrist instruments are not near a point where failures are likely to increase rapidly upon reaching Intutive's use limits. Especially in view of the life testing and repair procedures of Rebotix, Restore, Iconocare (and potentially SIS), EndoWrist instruments can likely be reset multiple times without degradation in performance. The specified careful incoming inspection is an essential requirement before any repair. Each EndoWrist submitted for repair requires an inspection to determine if any have damage or wear that makes that device ineligible for the specified repair process. I note once again the importance of the initial inspection and screening to identify all EndoWrists that are not suitable for repair. This inspection and screen is critical. There are many EndoWrists that are damaged and appear in the RMA database with remaining uses on the use counter. These EndoWrists are a part of the RMA data for a variety of

reasons including dropping, "sword fighting," damage from other EndoWrists, etc. Damage to an EndoWrist can happen at any number of uses on the use counter, even ten (10) uses on the use counter, and there is no data indicating that such damage is more likely after Intutive's use limit than before, particularly with a robust repair process.

XIII. THIRD PARTIES HAVE SHOWN THE ABILITY TO PROVIDE SOME MAINTENANCE AND REPAIR SERVICES FOR THE DA VINCI ROBOT

289. Dr. Howe opines that "the procedures performed by Restore to 'service da Vinci surgical systems contain significant deficiencies that do not allow proper maintenance or repair of da Vinci surgical robots . . . ."[334] In my opinion, although there were certain limitations to Restore's service offerings, Restore demonstrated the ability to provide some maintenance and repair services for the da Vinci robot.

290. As an initial matter, one requirement for the service and repair of surgical equipment is experience and training. [redacted].[335] [redacted].[336]

291. Dr. Howe opines that many of the steps in the preventative maintenance procedure must be performed using proprietary Intuitive software.[337] However, Dr. Howe acknowledges that

[334] Howe Hospital Report ¶ 28; *see also id.* ¶¶ 165-196.
[335] Parker depo. (*Restore*) tr., 91:21, 92:4, W. Gordon depo. (*Restore*) tr., 38:3-39:1; Restore-00001619, at 1619-1620; Restore-00001679, at 1681 and at 1689-1691.
[336] May depo. (*Restore* 5/6/21) tr., 18:14-20:15.
[337] Howe Hospital Report ¶ 169.

"certain steps in the preventative maintenance can be performed using visual checks and inspections (e.g., cord and cable inspections, monitor and illuminator checks, core inspection for dust accumulation) . . ."[338] Indeed, Intuitive's preventative maintenance procedures confirm that a number of the steps can be performed with the system offline.[339]

292. [redacted].[340] [redacted].[341] [redacted][342]

293. [redacted].[343] [redacted]

338 *Id.*
339 Intuitive-00705351, at Intuitive-00705357.
340 Restore-00025717; Intuitive-00705351.
341 W. Gordon depo. (*Restore*) tr., 208:2-12; 209:8-20; 210:16-25; 223:21-224:11.
342 W. Gordon depo. (*Restore*) tr., 54:18-55:11.
343 Parker (Oct. 25, 2022) depo. tr., 160:14-161:3.

[redacted][344] In fact, while Intuitive's service manuals required system verification to replace some parts, other parts could be replaced without system verification.[345]

294. Although Dr. Howe criticizes Restore's service offerings, the hospitals that sought these services from Restore disagreed. Restore was upfront and transparent with its customers about what services it could and could not perform.[346] Restore's customers understood these limitations, and yet they still envisioned using Restore for certain repairs that did not require Intuitive's software.[347]

Dr. T. Kim Parnell, PE

March 1, 2023

[344] Parker depo. (*Restore*) tr., 96:11–25.
[345] *See, e.g.*, Intuitive-00291402; Intuitive-00290657.
[346] Wasify Dep. Ex. 7, at AHS_MGMT-INTUITIVE_0000318-319.
[347] Wasfy depo. (Restore) tr., 28:5–29:13.

ATTACHMENT A

***Curriculum Vitae* of T. Kim Parnell**

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Expertise Highlights

- Medical device/biotechnology – Cardiovascular, Orthopedic, Orthodontic
- Patents & Intellectual Property
- Product Liability; Personal Injury
- Bluetooth, Zigbee, Wireless technology
- System Specifications & Test Procedures
- Composite Materials Design & Damage;
- Plastics, Molding, Manufacturing
- Telephone set design; touchpads; keypads
- Piezoelectric components
- Consumer Electronics & Products
- Laptop computers; keyboards; displays
- Materials & Metallurgy
- Failure Analysis & Reliability
- Fracture & Fatigue
- Numerical Multi-Disciplinary Analysis
- Digital Twin Technology Applications
- User experience & system interaction
- User interface design
- Finite Element Analysis of Structures & Fluid/Heat Transfer (FEA/CFD)
- Structural Mechanics, Fluid Mechanics, Heat Transfer, Thermodynamics
- Transducers, Accelerometers, MEMs
- Software design, development, QA
- Green energy: Wind, Solar Trackers, PV Panels; Electric Vehicles, Battery tech
- Shock & Vibration Sensitivity
- Vehicle & Heavy-Truck Crashworthiness
- ATV & Vehicle Design, Crashworthiness
- Group Manager & Project Leader;
- Strategic & Budgetary Planning responsibility
- Simulation Data Management

Education

Year	University	Degree Awarded
1984	Stanford University	Ph.D., Mechanical Engineering
1979	Stanford University	MSME, Mechanical Engineering
1978	Georgia Tech	BES, Engineering Science & Mechanics (Highest Honors)
2004	San Jose State University	Silicon Valley Executive Business Program (SVEBP)

Ph.D. Thesis: "Numerical Improvement of Asymptotic Solutions and Nonlinear Shell Analysis", June, 1984.

Professional Associations and Achievements

- Registered Mechanical Engineer (PE, M025550) in the State of California
- ASME Fellow; American Society of Mechanical Engineers (ASME)
- IEEE Senior Member; Institute of Electrical and Electronics Engineers (IEEE)
- Society of Automotive Engineers (SAE), Member
- ASM International Member; SMST (Shape Memory and Superelastic Technologies) Member; EDFAS (Electronic Device Failure Analysis Society) Member
- IEEE-SCV Santa Clara Valley Section Leadership Award; 2018
- IEEE Santa Clara Valley (IEEE-SCV) Section; Chair-2011, Vice Chair-2010
- IEEE Consultants' Network of Silicon Valley (IEEE-CNSV), Board Member; Chair: 2008-2009
- NAFEMS Member – Composite Materials Working Group (CWG), Vice-Chair
- IEEE Vehicular Technology Society (IEEE-VTS); Vice-Chair, 2012-2018; Treasurer 2018-present
- IEEE Consumer Electronics Society (IEEE-CE), IEEE Computer Society, IEEE Engineering in Medicine & Biology (IEEE-EMBS), IEEE Electronics Packaging Society (IEEE-EPS)
- Reviewer: *Journal of Composite Materials (JCM); International Journal of Forensic Engineering (IJFE); International Journal of Technology Transfer and Commercialization (IJTTC).*
- Chinese American Semiconductor Professional Association (CASPA)

Employment History

From: 2000 **Parnell Engineering & Consulting (PEC)**
To: Present Sunnyvale, CA; Web: *parnell-eng.com*
Position: *Principal & Founder*

Provides independent engineering consulting & expert witness services for high-technology applications including:

- Medical device/biotech product development & concept design
- Medical device cardiovascular applications across wide product range
- Medical device orthopedic, spinal, prosthetic devices – IP, design
- VC technical due-diligence for prospective medical device investment
- Patent & intellectual property – litigation, IPR, research, due diligence
- Expert Witness & Litigation Support services – multiple technologies
- Nitinol, shape-memory applications; biomaterials applications
- Portable devices, keypads: robust design, reliability & durability
- Cell phone Li-Ion battery failure & fire; protective enclosures;
- Bluetooth, Cellular, Zigbee, Wireless technology
- Solar panel tracker technology; PV Panel technology
- Manufacturing technology; materials applications (metals, polymers)
- Reliability and failure analysis services; accelerated testing
- Research in application & damage of composite materials
- Teaching intensive workshops & training seminars on simulation, design, and reliability for practicing engineers
- Lecturer in Prof. Steve Tsai's *Stanford Composites Design Workshop*
- Composite materials design & applications
- Wind Energy, Solar Energy, Alternative Energy – technology
- Electric vehicles, battery systems: design & development
- Heavy-Truck Rollover, Vehicle & ATV Crashworthiness; Barriers
- Software design, development, user experience, QA, testing
- Applications of CAE, FEA, and High-Performance Computing (HPC)
- Digital Twin Technology—FEA Simulation & Test

From: 2010 **Santa Clara University**
To: 2012 Santa Clara, CA
Position: *Faculty, Mechanical Engineering Department*

Taught courses covering a range of topics including Materials Science, Manufacturing Methods, Composite Materials, Finite Element Methods, Mechanism Dynamics, Computer Graphics, & Design. Advised students on Design, Safety, and Simulation for Student Projects including SAE Formula-Hybrid Vehicles. Research in Composite Materials and High-Performance Computing. Interaction with Industry Advisory Board (IAB) & ABET Certification. Teamed with other faculty for strategic initiatives and equipment/tool grants for research. Promote IEEE, ASME, cross-disciplinary initiatives & social media avenues for student networking, professional development & project support.

From: 2006 **MSC Software Corporation**
To: 2010 Sunnyvale, CA
Position: *Senior Manager, User Experience; Lead Application Engineer*

Integrated feedback from customers into user interface design & specifications; Beta testing of prototypes with users; CAE software Product Management role for user interface and analysis tools including:

- Product quality, testing, and improvement; drove customer satisfaction
- Application of advanced analysis technology in design & manufacturing
- Led corporate Wind Energy initiative & revival of Fatigue product
- Composite materials – acknowledged corporate & customer expert
- Customer training courses, workshops, webinars; developed & taught
- Software design, development, QA, testing of commercial apps
- Mentoring and development of junior staff; interviewed & hired staff for India; developed and trained staff using distance learning

Applied finite element technology to applications including automotive, medical device, energy, and electronics. Created customer satisfaction via:

- Customer support & analysis process development; Digital Twin
- Material testing & data reduction for development of properties

From: 1999 **Rubicor Medical, Inc.**
To: 2000 Redwood City, CA
Position: *Director of R&D*

Led the R&D team for this start-up medical device company developing breast diagnostic and therapeutic devices. Designed device considering interaction of Physician with Device and human factors. System included a mechanical subsystem and RF generator/control electronics. Developed initial prototypes and conceptual designs; researched IP and competing technologies.

From: 1986 **Exponent, Inc. and Failure Analysis Associates (FaAA)**
To: 1999 Menlo Park, CA
Position: *Senior Managing Engineer*

Delivered consulting services for failure analysis, accident investigation, product liability, patent/IP, insurance-related litigation, medical device and biotechnology product development, FDA submission, and forensic/failure investigation. Performed analyses involving stress, thermal, & fluid applications; testing of material properties and use of laboratory techniques such as SEM & Optical Microscopy for inspection of material samples. Led the SAE Heavy Truck Crashworthiness, Phase II project with testing & simulation of heavy-truck cabs in rollovers. Managed the Engineering Analysis Group and had profit/loss responsibility for the Engineering Computer Center. Maintained high personal utilization/billable hours and had increasing personal/group profitability with consulting services revenue generation >$600K.

From: 1995 **Stanford University**
To: 1996 Stanford, CA
Position: *Visiting Associate Professor, Mechanical Engineering Department*

Taught graduate courses in Theory of Plates and Theory of Shells in the Applied Mechanics Division (now Mechanics & Computation) of Mechanical Engineering. Part-time appointment while full-time staff-member at Exponent.

From: 1984 To: 1986 Position:	**SST Systems, Inc.** Sunnyvale, CA *Principal Engineer in Pressure Vessels, Piping & Structures Division* Managed software development, facilitated university collaboration, developed product specifications and enhancements based on customer feedback, supported and trained over 30 new customers, and created standardized product documentation. Provided sales and technical marketing support to CEO during product launch; formulated go-to-market campaign.
From: 1980 To: 1984 Position:	**Stanford University** Stanford, CA *Research Assistant, Mechanical Engineering Department* Established the theoretical basis and developed computational tools for nonlinear shell mechanics. Emphasized computational mechanics and engineering applications, including linear & nonlinear finite element methods and other numerical analysis techniques. Algorithm & software development
From: 1978 To: 1980 Position:	**AT&T Bell Laboratories** Indianapolis, IN *Member of Technical Staff (MTS), Physical Design Group* Design, development, and manufacturing of high-volume telecommunication components. Researched and designed dials, keypads, electromechanical systems, and piezoelectric polymer applications. Employed range of materials including elastomers, metals, polymers, and piezoelectrics for keypad and transducer applications. Emphasis on cost, reliability, and manufacturing simplicity. Developed new technologies to ultimately drive field improvements. Applied finite element simulation to improve designs and reduce prototypes.
From: 1976 To: 1977 Position:	**General Motors Corporation** Atlanta, GA *Engineering Assistant, Plant Engineering Department* Production line design and manufacturing applications for the GM Lakewood assembly plant. Supervised demolition and production line installation during changeover. Installed automated spotweld robot for sheet metal panels. Studied automotive manufacturing & assembly operations from start to finish.

Selected Grants & Research Programs

SA Photonics, Inc.

- 2013 – Phase I Navy SBIR – Post-IED Hull Inspection Tool, Topic N123-156

Stanford University

- 2012 – Phase II Army SBIR – Development and Implementation of Micro-Mechanics of Failure (MMF) Model for Composites in Commercial Finite Element Codes

Santa Clara University

- 2012 – Kuehler Summer Undergraduate Research Grant – student support for composite materials testing & characterization
- 2011 – Technology Innovation Grant – Acquisition of advanced DSC/TGA System for improved lab capability
- 2011 – Technology Innovation Grant – Acquisition of High-Performance Workstation for advanced simulation of large dynamic and nonlinear systems
- 2011 – Technology Innovation Grant – Materials Laboratory equipment upgrades and reorganization

Selected Presentations

"SMA Seismic Damping Devices: Fabrication, Testing, Analysis, and Projections", SMST-2014, Monterey, CA, May, 2014.

"Mechanical Design for Reliability: What does it Mean?", ASME Santa Clara Valley Section, Sunnyvale, CA, Mar, 2014.

"Prosthetic Feet using Carbon Fiber Composites: Design, Simulation, & Testing", ASME Santa Clara Valley Section, Jun, 2013.

"Mechanical Design for Reliability: Beating the Tough Problems", IEEE-SCV Reliability Society, Santa Clara, CA, Jun, 2013.

"Prosthetic Feet using Carbon Fiber Composites: Design, Simulation, & Testing", MSC Software 50th User Conference, Irvine, CA, May, 2013.

"Composite Materials: Improved Understanding of Composite Failure Mechanisms with DIC Testing & Analysis", Trilion User Conference, Philadelphia, PA, Sep, 2012.

"Medical Device Failures – 'Not so Good, Very Bad, and Truly Ugly'!!", ASM (Materials Information Society) Santa Clara Valley Chapter, May, 2012.

"C-Ply Bi-Angle NCF Tape Seam Assessment & Design Considerations for Automated Tape Laying", Composites Design Forum, JEC Composites Conference, Paris, Mar, 2012.

"Failure of Structures Designed with Composite Material – Delamination", *'Meet the Experts' Forum on Composite Materials*, Joint with Prof. Steve Tsai, SMP Tech, Feb 28, 2012.

"Shape Memory Alloy Fundamentals & Advanced Simulation Techniques for Medical Products", *'Meet the Experts' Forum on Nitinol Properties and Unique Behavior for Medical Product Design*, SMP Tech, Sep 14, 2011.

"Stiffness and Strength of Laminates Fabricated with Bi-Directional Tape", ICCM-18 (International Conference on Composite Materials, Korea, Aug, 2011, (with Daniel D. Melo & Christine Tower))

"Composite Materials – Damage & Delamination", Santa Clara University, Mechanical Engineering Seminar, Feb, 2011

"Composites Damage, Delamination, Failure & Curing" and "Workshop on Mic-Mac/FEA" with Prof. Steve Tsai, Stanford Composites Design Workshop, 2010-2012

"Composite Damage, Delamination, and Failure" and "Workshop on Mic-Mac/FEA" with Steve Tsai, Stanford Composites Design Workshop, Jan, 2010

"Composite Failure Methods – Application Comparisons", Composites Durability Workshop-14 (CDW-14), UCLA, Jul, 2009

"Composites Damage, Delamination, and Failure Analysis", Stanford Composites Workshop, May 2009

"Finite Element Analysis using a Thermomechanical Shape Memory Alloy Model", SMST-2006, Monterey, CA, 2006.

"Medical Device Issues & Trends", in "Biomedical Wave: Opportunities for Non-Biologists**",** MedTech Bridge Seminar Series, 2005.

"Medical Device Development and Entrepreneurship", IEEE Consultants' Network of Silicon Valley (IEEE-CNSV), *www.CaliforniaConsultants.org* , 2004.

"CFD Fundamentals and Applications in Biotechnology", ASME Professional Development Seminar, 2003 & 2004.

"Medical Device Business Opportunities in China", multiple presentations to key government and industry representatives, CASPA Delegation, Oct, 2003.

"Using Simulation with Testing for Maximum Benefit", WESCON 2003, Low Cost Tools: Alternatives for Problem Solving in Development, Design and Application, San Francisco, CA, Aug, 2003.

"Fracture Mechanics: Overview and Applications", Aeronautics & Astronautics Department, Stanford University, May, 1999.

"Integrated Fluid/Thermal/Structural Analysis of a Turbine Blade", American Society of Mechanical Engineers Bay Area Technical Conference, May, 1995.

"Failure Analysis Projects", Mechanical Engineering Department, Stanford University, May. 1992.

"Finite Element Applications in Failure Analysis", Mechanical Engineering Department, Stanford University, Mar, 1991.

"Soil-Pipeline Interaction Associated with a Process-Plant Explosion", Seminar in Solid Mechanics, Stanford University, Nov, 1989.

"*Typical* Failures: Causes and Consequences", Construction Engineering and Management Program, Civil Engineering Department, Stanford University, 1989.

"Shell Analysis Using Personal Computers", Solid Mechanics Seminar, Stanford University, 1985.

Selected Publications

"Numerical evaluation of SMA-based multi-ring self-centering damping devices.", (2021). Smart Materials and Structures. DOI: *https://doi.org/10.1088/1361-665X/ac1d94*. (with M. Salehi, R. DesRoches, and D. Hodgson).

"Numerical Simulation of Seismic Response Control of Frame Structure Using High-Temperature Shape Memory Alloy Wire"; Proceedings of: International Conference on Earthquake Engineering (SE-50EEE), At MAEE, Skopje, Macedonia, May 2013, (with Md. Golam Rashed and Raquib Ahsan).

"Equivalent Properties for Finite Element Analysis in Composite Design", JEC Composites Magazine, No.68 (Bi-Angle NCF Special Issue), Oct, 2011, (with Stephen W. Tsai)

"Stiffness and Strength of Laminates Fabricated with Bi-Directional Tape", ICCM-18, Aug, 2011, (with Daniel D. Melo & Christine Tower)

"How Reliable Is Your Product: 50 Ways to Improve Product Reliability", Mike Silverman, 2011 (2-Book Chapters contributed by T. Kim Parnell).

"Heavy Truck Roll Cage Effectiveness", IMECE2009-12423, Proceedings of IMECE: ASME-Mechanical Engineering Congress and Exposition, Nov, 2009, (with Stephen Batzer, Bruce Enz, Grant Herndon, Chandrashekar Thorbole, Robert Hooker, and Mariusz Ziejewski).

"Composite Failure Methods – Application Comparisons", Proceedings of Composites Durability Workshop-14 (CDW-14), UCLA, Jul, 2009

"Thermoelastic Shape Memory Modeling of Medical Devices with FEA", SMST-2006, The International Conference on Shape Memory and Superelastic Technologies, ASM International, May, 2006, (with Sanjay Choudhry and Jesse Lim).

"Finite Element and Fatigue Analysis of CardioVasc Stent Graft", CardioVasc, Inc., 2004.

"Analysis of Rail Cracking and Development of a Rail Screening Guideline Based on Fracture Mechanics Principles", Fatigue & Durability Assessment of Materials, Components & Structures, Proceedings of the Fifth International Conference of the Engineering Integrity Society, Queen's College, Cambridge, UK, Apr 7-9, 2003.

"Finite Element and Fatigue Analysis of CP Stent Expansion", NuMed, Inc., 2003.

"Evaluation of a Failure in a Chlorine Production Facility", Proceedings of IMECE 2001, ASME International Mechanical Engineering Congress and Exposition, Nov, 2001, New York, NY (with S. Andrew, R. Caligiuri, and L. Eiselstein).

"Physical Testing for Good Analysis: Experimental Validation for Quality Finite Element Analysis of Medical Devices", feature article for *ANSYS Solutions*, Fall 2000 (Machine Design Custom Media, Penton Media, Inc.).

"Finite Element Simulation of 180° Rollover for Heavy Truck Vehicles", ASCE Engineering Mechanics Conference, Baltimore, MD, Jun, 1999 (with Christopher V. White and Shari E. Day).

"Finite Element Analysis of the S670 Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1999.

"Finite Element Analysis of the S660 Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1999.

"Finite Element Analysis of the Six Crown Extra Support Renal Stent – Minimum Dimensions", Arterial Vascular Engineering, Inc., 1998.

"Finite Element Analysis of the SVG Stent", Arterial Vascular Engineering, Inc., 1998.

"Finite Element Analysis of the GFX-II Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1998.

"Analysis of Drill Pipe Joint Failures and Recommendations For Service", Failure Analysis Associates, Inc. Report, Nov, 1997 (with R.D. Caligiuri, L.E. Eiselstein, M. Wu, R. Huet).

"Finite Element Analysis of the GFX Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1997.

"Stress Analysis: AVE MicroStent-II Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1997.

"SAE Report CRP-12 Heavy Truck Crashworthiness – Phase II (180° Dynamic Rollover, Static Roof Crush Simulation)", SAE Headquarters, 1997.

"Heavy Truck 180º Dynamic Rollover and Static Roof Crush Simulation", Failure Analysis Associates, Inc. Report, Apr, 1996 (with C. White, S. Day, T. Khatua, and L. Cheng).

"Fracture Toughness by Small Punch Testing", *Journal of Testing and Evaluation*, Vol. 23(1), pp. 3-10, Jan, 1995 (with J. R. Foulds, P. J. Woytowitz and C. W. Jewett).

"Safety Analysis of Custom Designed Manufacturing Equipment", Proceedings, American Society of Mechanical Engineers Winter Annual Meeting, Safety Engineering and Risk Analysis, New Orleans, Louisiana, Nov, 1993, Vol. 1, pp. 111 (with G. L. Rao and R. D. Caligiuri).

"American Azide Corporation Reactor and Dryer Safety Studies", Failure Analysis Associates, Inc. Report, Jan, 1993 (with G. L. Rao, V. B. Rao, and R. D. Caligiuri).

"Combustion Tests on and Chemical Analysis of Therminol 66 Heat Transfer Fluid Used at American Azide", Failure Analysis Associates, Inc. Report, 1993 (with A. Reza and R. D. Caligiuri).

"Gas Release from Leaky Natural Gas Pipeline: The PEPCON Explosion in Henderson, Nevada", Failure Analysis Associates, Inc. Report, 1992 (with A. Reza, M. El-Fadel and R. D. Caligiuri).

"Computational Modeling of Dynamic Failure in Armor/Anti-Armor Materials", Failure Analysis Associates, Inc. Final Report to U.S. Army Research Office, Contract DAA-L03-88-C-0029, May, 1992.

"Analysis of Cracking in the Windsor Recovery Boiler Superheater", Failure Analysis Associates, Inc. Report to Domtar, Inc., Apr, 1992 (with R. D. Caligiuri, C. H. Lange and S. P. Andrew).

"Analysis of the Dynamic Response of a Buried Pipeline due to a Surface Explosion", *Computational Aspects of Impact and Penetration*, L.E. Schwer and R.F. Kulak, eds., Elme Press International, 1991 (with R. D. Caligiuri).

"Failure Analysis of Aerzen Screw Compressor Male Thrust Bearings", Failure Analysis Associates, Inc. Report to AECI Chlor-Alkali & Plastics, Ltd., Sep, 1991 (with C. C. Schoof).

"Gas Flow and Heat Transfer in a Pipe Tee Joint", Failure Analysis Associates, Inc. Report to Chevron Corporation, Nov, 1990 (with R. D. Caligiuri and A. Reza).

"Development of Dynamic Failure Criteria for Ceramic Armor Materials", Failure Criteria and Analysis in Dynamic Response Symposium, ASME Winter Annual Meeting, Nov, 1990, H.E. Lindberg, ed.

"DYNA3D Analysis of the Dynamic Response of a Buried Pipeline due to a Surface Explosion", DYNA3D User Group Conference, Bournemouth, Dorset, United Kingdom, Sep, 1990.

"Con Edison Hellgate Facilities Gas Main Rupture", Failure Analysis Associates, Inc. Report to Consolidated Edison Company of New York, Inc., Feb, 1990.

"Stress and Fracture Mechanics Analysis of Weld Cracking in a Rotary Ball Mill", American Society of Mechanical Engineers Winter Annual Meeting, Paper 89-WA/DE-17, San Francisco, California, Dec, 1989 (with C. A. Rau, Jr., H. F. Wachob and E. L. Kennedy).

"Analysis of the Plunger-to-Plunger Rod Joint in an Automotive Fuel Injector", Failure Analysis Associates, Inc. Report to Hitachi, Ltd., Oct, 1988 (with P. R. Johnston and B. Ross).

"Analysis of the Circumferential Seam Weld Cracking of Raw Grinding Mills", Failure Analysis Associates Report to Kaiser Cement Corporation, Nov, 1986 (with C.A. Rau, Jr., H.F. Wachob).

"Local Flexibility and Stresses in Cylindrical and Spherical Shells Due to External Loadings on Nozzles and Lug Attachments", A.F.I.A.P. Conference, Paris, France, Oct, 1986.

"Analysis of Piping Systems with Local Nozzle Flexibility Using Personal Computers", American Society of Mechanical Engineers Pressure Vessel and Piping Conference, New Orleans, LA, 1985.

"Numerical Improvement of Asymptotic Solutions and Nonlinear Shell Analysis", Ph.D. dissertation, Stanford University, Jun, 1984.

"Numerical Improvement of Asymptotic Solutions for Shells of Revolution with Application to Toroidal Shell Segments", *Computers & Structures*, Vol. 16, No. 1-4, 1982.

Consulting Projects - Selected

Client: NanoBio Genomics, Inc.
Project: Confidential

Client: Aquedeon Medical, Inc.
Project: Product development associated with implantable Nitinol medical device for aortic aneurysm; Duett product; Radial Stiffness Assessment; Correlate Test & Simulation

Client: Silver Spring Networks, Inc.; Ops A La Carte LLC
Project: Mechanical Accelerated Life Testing and Reliability Assessment of Commercial IoT Network-Connected Natural Gas Metering Equipment; Failure Analysis support; plastic component design, accelerated life testing; remote monitoring;

Client: F-Prime Capital Partners (former Fidelity Biosciences)
Project: Technical Due-Diligence review of prospective stealth-mode medical device investment

Client: SI-Bone, Inc.
Project: Design review of iFuse sacroiliac (SI) joint fixation devices; Competitive comparison

Client: TexasLDPC, Inc.
Project: Business Advisor; Flash Memory Technology development for error-correction; LDPC – Low-Density Parity Check; start-up

Client: Cerevatech Medical, Inc.
Project: Business Advisor; Medical Device developer of innovative Nitinol neurovascular stent and flow diverter devices, start-up

Client: Promed Medical Inc.
Project: Evaluation of deployment failure associated with Nitinol scaffold and bioabsorable PLGA cover material. Test protocols; assessment of data and development of strategy to increase device reliability.

Client: Topera Inc.
Project: Evaluation of Nitinol device failure in test and clinical setting used for 3D mapping associated with treatment of arrhythmia. Comparison of current design with proposed redesign.

Client: LC Therapeutics
Project: Assessment of Nitinol coronary device.

Client: CrossRoads Extremity Systems
Project: Design evaluation of Nitinol orthopedic devices for bone fixation with focus on foot & ankle devices including staples and plates; Report for 510K submission to FDA

Client: Bridgelux, Inc
Project: Design evaluation of LED Outdoor Lighting Module (OLM) for assembly and service conditions; assessment of polymeric, injection-molded components including FRP (fiber-reinforced plastic)

Client: Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Project: MEMs Patent Portfolio review and assessment

Client: Design Standards Corporation (DSC)
Project: Design analysis & report for injection-molded surgical ligation clip;

Client: Sirius Engineering LLC
Project: Nitinol Vena-Cava Filter; Implantable cardiovascular medical device

Client: Nitinol Technology, Inc.
Project: Design and assessment of large-scale nitinol components for seismic damping in civil structures (buildings, bridges, roadways); analysis & testing collaboration

Client: Varian Medical, Inc.
Project: Medical radiation oncology capital equipment; shipping hazard assessment

Client: Atsina Surgical LLC
Project: Injection molded surgical ligation clip; material testing; product design, development, and optimization

Client: Home Dialysis Plus
Project: Development of reliability & accelerated testing protocols for innovative dialysis system including mechanical, electronic, & software components

Client: Freedom Innovations, LLC
Project: Carbon Fiber Prosthetic Foot – failure analysis, simulation

Client: Ops A La Carte LLC
Project: Mechanical Design for Reliability classes; failure analysis; simulation of mechanical & thermal performance; accelerated testing and root-cause analysis; TTi Sunseeker solar tracker failure analysis, redesign after full system loss due to damage from high winds;

Client: OLT Solar
Project: Product improvement under high-temperature exposure

Client: VX Aerospace
Project: Composite material product design and validation

Client: Fidelity Biosciences
Project: Medical device due-diligence and technology evaluation pre-investment

Client: DJS Associates
Project: Automated food packaging equipment - failure analysis and assessment of root cause issues

Client: Tribal Engineering, LLC
Project: Various simulation and customer training projects

Client: Gerson Lehrman Group
Project: MEMs Sensors; Various other projects

Client: Ops A La Carte LLC
Project: Various Reliability Consulting projects; Mechanical Design for Reliability Training

Client: Revascular Therapeutics, Inc (acquired by Boston Scientific)
Project: Implantable medical device for treatment of calcified lesions

Client: City and County of San Francisco
Project: Glass failure; Trial prep

Client: Sagalio LLC
Project: Retractable screen for portable cellular devices

Client: New Energy Technologies, Inc
Project: Alternative Energy concept assessment & review

Client: Square One Medical
Project: Implantable medical device design, development, simulation

Client: Kyphon
Project: Device improvement for spinal interventional device

Client: ProMed, Inc
Project: Implantable medical device for spinal application

Client: Nuvation
Project: Instrumentation assessment

Client: Ovalis, Inc
Project: Nitinol PFO Closure Device development and design improvements

Client: Gateway Medical
Project: Vascular Closure Device

Client: Ensure Medical
Project: Vascular Closure Device

Client: Abbott Laboratories
Project: Continued development and cost reduction aspects for StarClose device.

Client: Integrated Vascular Solutions (IVS) (acquired by Abbot Labs)
Project: Design & development of StarClose nitinol closure device for arterial closure following interventional procedures. 2005 MDM Excellence Award

Client: Prolifix Medical
Project: Nitinol device to excise plaque buildup from arteries

Client: Coapt Systems
Project: Bioabsorbable devices for surgical and cosmetic procedures

Litigation Support Experience

Litigation Cases; Depositions & Expert Reports as Shown:

2022 to Present	Client:	Haley Guiliano LLP
	Case:	*Surgical Instrument Service Company, Inc. v Intuitive Surgical, Inc.*, Case No. , United States District Court, Northern District of California
	Project:	Anti-Trust case associated with EndoWrist devices for Da Vinci surgical robots. Engineering evaluation of repaired devices.
	Status:	
2022 to Present	Client:	Spector Roseman & Kodroff, P.C.
	Case:	*RE: Da Vinci Surgical Robot Antitrust Litigation*, Lead Case No. 3:21-cv-03825-vc, United States District Court, Northern District of California
	Project:	Anti-Trust case associated with EndoWrist devices for Da Vinci surgical robots. Engineering evaluation of repaired devices.
	Status:	
2022	Client:	Calfee, Halter & Griswold, LLP
	Case:	*LG Electronics, Inc v. Multiple Respondents,* Certain Refrigerator Water Filtration Devices and Components Thereof, Investigation No. 337-TA-1290, United States International Trade Commission (ITC), Washington, D.C.
	Project:	ITC Investigation regarding alleged Validity and Infringement of 3 LGE patents for Refrigerator Water Filtration technology.
	Status:	Settled; Invalidity & Non-Infringement Declarations, June 2022. Deposition, July 2022.
2021 to 2022	Client	Banner Witcoff
	Case:	*Aspen Medical Products, LLC v Breg Inc.*Case No.3:21-cv-00631-WQH-MDD in the United States District Court, Southern District of California
	Project:	Patent matter regarding medical body and cervical support braces
	Status:	Settled.
2021 to 2022	Client:	Dovel & Luner, LLP
	Case:	*Rebotix Repair LLC v Intuitive Surgical, Inc.,* Case No. 8:2020cv02274, United States District Court, Middle District of Florida, Tampa Division.
	Project:	Anti-Trust case associated with EndoWrist devices for Da Vinci surgical robots. Engineering evaluation of repaired devices.
	Status:	Settled; Expert Report, Aug 2021; Deposition, Sep 2021;
2021 to 2022	Client	Gibson, Dunn & Crutcher, LLP
	Case:	Confidential Case – United States District Court, Central District of California.
	Project:	Patent matter associated with beverage systems and components
	Status:	Settled.

2021	Client:	Schlichter & Shonack, LLP
	Case:	*KV Inc v Heartstitch, Inc.,* Case No. 30-2019-01051080-CU-BC-NJC in the Superior Court for the State of California, County of Orange
	Project:	Assessment of FDA regulated custom manufactured medical device components for heart surgery. Assessment of conformance and quality.
	Status:	Settled
2021	Client:	Dentons, London, UK
	Case:	Confidential Case - *European Patent Office review*
	Project:	Medical device patent; Support review process
	Status:	European Patent Office (EPO) Declaration 2021;
2021 to Present	Client:	Rosen & Perry, P.C.
	Case:	*Chamber v. Dollar Tree Store, et.al.;* Case No. , Superior Court, Pennsylvania
	Project:	Personal Injury, warnings, device evaluation; – material and load evaluation of hair device; tissue damage due to pressure
	Status:	Ongoing.
2021 to Present	Client:	Cogan & Power, PC
	Case:	*Michele Volk v. Stryker Medical, et.al*
	Project:	Investigate microcatheter failure during medical procedure.
	Status:	Ongoing.
2021	Client:	Thompson Coburn LLP
	Case:	*Widdenmeyer v. Zoll Medical, Ranken-Jordan Hospital, et.al.* Case No. , Superior Court, St.Louis, MO
	Project:	Investigate alleged malfunction and defect in AED (Automated External Defibrillator). Site inspection.
	Status:	Resolved
2020 to Present	Client:	Klarquist Sparkman, LLP
	Case:	Various - Patent
	Project:	Medical device patent
	Status:	Ongoing.
2020	Client	Morrison & Foerster, LLP on behalf of Apple, Inc.
	Case:	In RE: Macbook Keyboard Litigation; Various Plaintiffs, vs. Apple Inc.; Case No. 5:18-CV-02813-EJD-VKD United States District Court Northern District of California, San Jose Division
	Project:	Potential Class Action and Class Certification; Laptop Keyboard technology; design, performance, repair rates.
	Status:	Expert Report, Sep 2020; Deposition, Oct 2020;

2020	Client:	Baker & Hostetler, LLP
	Case:	*NEXTracker vs. Solar FlexRack and Northern States Metals Co.,* United States District Court, District of Delaware
	Project:	Patents; Solar tracker technology patents associated with Guide Rails, Clamps, etc.
	Status:	Settled; IPR Declaration Oct 2020;
2020 to 2021	Client:	Merchant & Gould P.C.
	Case:	*Otter Products, LLC and Treefrog Developments, Inc. vs Fellowes, Inc.* United States District Court, Northern District of Illinois, Eastern Division;
	Project:	Patents; Consumer Electronics technology for protection of personal electronics (cell phones, tablets, etc.) against drop, moisture, etc.
	Status:	Settled; IPR Declarations: 2-Aug 2020; 2-Dec 2020; 1-Jan 2021; Patent Infringement;
2020 to 2022	Client:	Bienert Katzman PC
	Case:	*Julie Hall, vs. Torax Medical, Inc., Ethicon, Inc., Johnson & Johnson, John Lipham, MD, et.al,* Case No. 30-2019-01078281-CU-PL-CJC in the Superior Court for the State of California, County of Orange
	Project:	Personal injury, product liability associated with medical device to treat Gastric Reflux Disease (GERD)
	Status:	Settled
2020 to Present	Client:	The Cottle Firm
	Case:	*Richard vs. American Honda Motor Co., Inc., Home Depot USA, Inc., et.al.* Case No. A-19-791675-C in the Nevada State District Court, Clark County, Nevada
	Project:	Personal injury, product liability associated with rototiller
	Status:	Deposition Nov 2021; Expert Report May 2020, Aug 2021; Ongoing.
2020 to Present	Client:	Todd Tracy Law Firm
	Case:	*Hendricks v DTNA, Freightliner. et.al*; Cause No. 103610-86 in the District Court, Kaufman County, TX, 86th Judicial District
	Project:	Heavy-truck rollover & crashworthiness; design assessment; product liability
	Status:	Ongoing.
2020	Client:	Todd Tracy Law Firm
	Case:	*Guerra v Navistar*; Case No. 1:18-CV-00321-KG-JFR, United States District Court for the District of New Mexico
	Project:	Heavy-truck rollover & crashworthiness; design assessment; product liability
	Status:	Deposition, Aug 2020; Settled

2019 to 2020	Client:	Singer Davis LLC
	Case:	*McIntosh vs. EVMS Academic Physicians & Surgeons Health Services Foundation, Covidien Holding, Inc., Cook Medical, LLC, et.al.* Case No. CL18-4817 in the Circuit Court for the City of Norfolk Virginia
	Project:	Personal Injury, Product Liability related to Percutaneous Tracheostomy Tube;
	Status:	Settled
2019	Client:	Venable LLP
	Case:	*Disc Disease Solutions, Inc., vs. VGH Solutions, Inc. Dr-Ho's Inc., Hoi Ming Michael Ho.* Case No. 1:15-cv-00188-LJA, United States District Court, Middle District of Georgia, Albany Division
	Project:	Patents; Medical Device, Back-Pain Relief;
	Status:	Settled; Claim construction, invalidity, non-infringement; Claim construction Declaration Aug 2019;
2019	Client:	Baker & Hostetler, LLP
	Case:	*Zadro Products, Inc. vs. SDI Technologies, Inc. d/b/a iHOME.* Case No. 17-1406 (WCB) in the United States District Court for the District of Delaware
	Project:	Patents; Consumer products, LED lighting, mirrors
	Status:	Settled
2019	Client:	Gardella Grace P.A.
	Case:	*Fulfillium, Inc. vs. ReShape Medical, LLC, SV Health Investors, LLC, Intersect Partners, LLC and ReShape Lifesciences, Inc.* Case No. 8:18-cv-01265-RGK-PLA United States District Court, Central District of California, Western Division
	Project:	Patents; medical devices, balloons, weight control
	Status:	Settled; Deposition Aug 2019; Expert Report Aug 2019; Declaration on Motion for Summary Judgement Aug 2019;
2019	Client:	Merchant & Gould
	Case:	*Carlson Pet Products, Inc. v. North States Industries, Inc..* Case No. 17-cv-02529- PJS-KMM, United States District Court for the District of Minnesota
	Project:	Patents, Consumer product; Pet barrier
	Status:	Settled; Declaration, Oct 2019;
2019 to Present	Client:	Todd Tracy Law Firm
	Case:	Multiple cases
	Project:	Heavy-truck rollover & crashworthiness; design assessment; product liability
	Status:	Ongoing.

2019	Client:	Sterne, Kessler, Goldstein & Fox, P.L.L.C. (SKGF)
	Case:	*Lutron v. Geigtech*
	Project:	Patent Post-Grant Review (PGR); Other PTAB actions
	Status:	Suspended
2019 to Present	Client:	Faegre Baker Daniels LLP
	Case:	Confidential MDL Product Litigation
	Project:	Confidential
	Status:	
2019 to 2022	Client:	Rouda Feder Tietjen McGuinn
	Case:	*Margo Schein v. Peak Pilates*
	Project:	Inspection of Pilates Reformer equipment; Accidental injury root-cause assessment; explain accident scenarios; Support for mediation;
	Status:	Resolved;
2019	Client:	Manning & Kass, Ellrod, Ramirez, Trester LLP
	Case:	*Randy and Giselle Hoehn v. Summit to Sea LLC, Pet Pressure LLC.*
	Project:	Hyperbaric pressure chamber inspection, operation, and design review. Accidental injury investigation.
	Status:	Settled
2018 to 2020	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Miriam Naramore v. Daimler Trucks North America, LLC.* Civil Action No. 1:18-CV-00156 in United States District Court for the Middle District of Georgia, Albany Division.
	Project:	Heavy-truck rollover & crashworthiness; design assessment
	Status:	Settled
2018 to 2021	Client:	Maddin, Hauser, Roth & Heller, P.C.
	Case:	*Larry Esckilsen and Renie Esckilsen v. Oakland Orthopedic Appliances, Inc.;* Case No. 18-036354-NO-1 Saginaw Circuit Court
	Project:	Alleged failure of orthopedic leg prosthetic; personal injury
	Status:	Settled; Deposition, Sep 2020;
2018 to 2019	Client:	Klein, DeNatale, Goldner, LLP
	Case:	*H&M Gopher Control, Allen Hurlburt v. Benchmark Pest Control, Inc., Andrew Ozanich.* Case No. 1:17-CV-01700-JLT, United States District Court for the Eastern District of California
	Project:	Patent technology for control of rodents
	Status:	Settleld; Expert Report, Jan 2019;
2018 to 2019	Client:	Cypress LLP
	Case:	*Kore Essential, Inc v. Nexbelt, LLC.* Case No. 3:17-CV-02129-CAB-JMA, United States District Court for the Southern District of California
	Project:	Patent technology for Ratchet Belt system
	Status:	Settled; Expert Report, Feb 2019;

2018 to 2019	Client:	Pillsbury Winthrop Shaw Pittman, LLP
	Case:	*Lite-On Technology Corp v Darfon Electronics Corp,* Case No. 3:18-cv-02776, United States District Court, Northern District of California.
	Project:	Keyboard technology patents
	Status:	Settled; IPR Declaration Dec 2018;
2018 to 2020	Client:	Honigman Miller Schwartz & Cohn LLP
	Case:	*Tim A. Fischell, Robert E. Fischell, and David R. Fischell v. Cordis Corp, Abbott Laboratories and Abbott Cardiovascular Systems, Inc.*, United States District Court for the District of New Jersey; Civil Action No. 3:16-cv-00928-PGS-LHG
	Project:	Patent family associated with cardiovascular stents
	Status:	Settled; Declaration, Apr 2019;
2018	Client:	Akerman, LLP
	Case:	*Qbex Computadores S.A v. Intel Corporation,* United States District Court, Northern District of California, San Jose Division.
	Project:	Cellular phone ARM microprocessor, alleged product design defect associated with CPU overheating
	Status:	Settled
2018 to 2019	Client:	Davidson, Davidson & Kappel LLC
	Case:	ArcelorMittal Project; *Inter Partes Review Proceeding Against Array Technologies Inc. U.S. Patent 8,459,249*
	Project:	Patent IPR associated with solar panel trackers
	Status:	Settled; Deposition Dec 2018; IPR Declaration Mar 2018;
2018 to 2019	Client:	Ropes & Gray LLP
	Case:	*CPI Card Group, Inc. v. Multi-Packaging Solutions, Inc* , United States District Court for the District of Colorado
	Project:	Patent associated with secure packaging of transaction/gift cards; Testing
	Status:	Resolved
2017 to 2018	Client:	Rimon Law
	Case:	*Imogene D. Johns v. Invacare Corporation,* Tulare County Superior Court Case No. 270201
	Project:	Alleged medical equipment product defect
	Status:	Settled
2017 to 2018	Client:	The Scranton Law Firm
	Case:	*Cesar Lopez & Moses Sepulveda v. DOES-1*
	Project:	Alleged design defect in ATV Rollover Protection System (RoPS); Design and Failure Analysis
	Status:	Resolved;

2017 to 2018	Client:	Troutman Sanders LLP; Vinson & Elkins
	Case:	*Blackbird Tech LLC d/b/a Blackbird Technologies v. Lenovo (United States) Inc.;,* C.A. No. 16-cv-140-RGA, United States District Court for the District of Delaware
	Project:	Patent infringement allegations around laptop computer screen display technology
	Status:	Settled; Declaration May 2018; Deposition Feb 2018; Reply Report Dec 2017; Non-Infringement Report Nov 2017; Invalidity Report Sep 2017;
2017	Client:	White & Case LLP
	Case:	*Maquet Cardiovascular LLC v. Abiomed Europe GmbH and Abiomed R&D, Inc.*; C.A. No. 1:16-CV-10914, United States District Court for the District of Massachusetts
	Project:	Resolved; Multiple Patent & Technology dispute associated with Implantable Circulatory Support System Pumps
2017 to 2018	Client:	Baker & Hostetler, LLP
	Case:	*SCA Hygiene Products AB et.al., SCA Tissue North America, LLC v. Tarzana Enterprises, LLC;* United States District Court, Western District of Wisconsin, No. 3:16-cv-00728
	Project:	Patent infringement claims associated with paper goods manufacturing, stacking, folding, and packaging methods and equipment
	Status:	Settled; Depositions (2) Sep 2018; IPR Response Declarations, Jul 2018 (2), May 2018;
2017	Client:	Vinson & Elkins
	Case:	*Inter Partes* Review of U.S. Patent No. 7,129,931; *Lenovo (United States) Inc. v. Blackbird Tech LLC d/b/a Blackbird Technologies; Blackbird Technology LLC v. Lenovo, Civil Action No. 1:16-cv-00140 in the District of Delaware*
	Project:	Patent IPR and alleged infringement involving laptop computer display apparatus
	Status:	Deposition Feb 2018; Expert Report; IPR Declaration May 2017;
2017 to Present	Client:	The Joe C. Savage Law Firm
	Case:	*Bauer v. Parks, Hyundai Motors America, and Deskins Motor Company and other related cases;*
	Project:	Vehicle Accident Investigation, Design, Crashworthiness, Fire
	Status:	Settled

2017 to 2018	Client:	Hill, Kertscher & Wharton, LLP
	Case:	*Trans Technologies Company v. Hendrickson USA LLC, et.al.*, United States District Court for the Northern District of Georgia, Atlanta Division, Civil Action No. 1:16-cv-01778-AT
	Project:	Patent litigation involving heavy-truck tire inflation/deflation technology
	Status:	Settled; Deposition Jul 2018; Deposition Apr 2018; IPR Declaration Aug 2017; IPR Reply Declaration Feb 2018;
2017 to 2018	Client:	Morgan, Lewis & Bockius LLP
	Case:	*Advanced Circulatory Systems, Inc. v. AutoMedx, Inc.,* and *AutoMedx, Inc v. ZOLL Medical Corp., Advanced Circulatory Systems, Inc.;* CPR Institute for Dispute Resolution, CPR File No. G-16-07
	Project:	Medical Ventilator Technology Development; Medical equipment
	Status:	Settled
2017	Client:	Dorsey & Whitney LLP
	Case:	*Hovik Nazaryan v. FemtoMetrix Inc.*, Superior Court of the State of California for the County of Orange Case No. 34-30- -2015-00795246-CU-BC-CJC
	Project:	Semiconductor lithography equipment technology development
	Status:	Settled
2016 to Present	Client:	Casper, Meadows, Schwartz & Cook
	Case:	*Rovner v. Medtronic, Inc. et.al.* Contra Costa Superior Court, Case No. C16-01768
	Project:	Medical Device defect of NSC spinal lumboperitoneal (LP) Shunt/Valve for hydrocephalus shunting of excess cerebrospinal fluid (CSF); associated personal injury
	Status:	Settled
2016 to 2018	Client:	Rimon Law
	Case:	*Heather Ciechanowski v. Invacare Corporation, Folsom Care Center, Bluff Enterprises, Inc. and Calvin Callaway*, Sacramento County Superior Court Case No. 34-2016-00188724
	Project:	Alleged medical equipment product defect
	Status:	Settled
2016 to 2017	Client:	Rucka, O'Boyle, Lombardo & McKenna
	Case:	*Concepcion Hernandez v. Helen of Troy, Inc;*
	Project:	Medical equipment personal injury
	Status:	Settled

2016 to 2017	Client:	Quinn Emanuel Urquhart & Sullivan, LLP
	Case:	*TriReme Medical LLC v. AngioScore, Inc.*, Northern District of California; Case No. 14-cv-2946
	Project:	Patent litigation involving cardiovascular medical device
	Status:	Deposition, Dec.2016; Expert Reports, Nov.2016 & Dec.2016; Settled
2016 to 2017	Client:	Baker Manock & Jensen, PC
	Case:	*California Fire-Roasted LLC v. General Mills Operations, LLC;* Sacramento County Superior Court Case No. 34-2014-00170784-CU-BC-GDS
	Project:	Patent licensing and royalty case for food-processing equipment
	Status:	Settled
2016 to 2017	Client:	DLA Piper, LLP
	Case:	*Inter Partes* Review of U.S. Patent No. 6,099,882; *Olam West Coast, Inc. v. California Fire-Roasted LLC*
	Project:	Patent IPR involving food-processing equipment
	Status:	Settled; IPR Declarations (2) Oct.2016;
2016 to 2018	Client:	Plews Shadley Racher & Braun, LLP; Bradshaw Law, LLC
	Case:	*Rick C. Sasso, M.D., and SEE LLC v. Warsaw Orthopedic, Inc., Medtronic Inc., Medtronic Sofamor Danek, Inc*, Indiana State Court, Case No. 43C01-1308-PL-44.
	Project:	Patent litigation involving coverage for spinal medical device
	Status:	Deposition Aug 2018; **Patent Trial Testimony Nov 2018**; Jury Verdict for Plaintiff; Upheld on Appeal Dec 2020;
2016 to Present	Client:	Christensen Fonder, P.A.
	Case:	*Willis Electric Co., Ltd v. Polygroup Limited (Macao Commercial Offshore), Polygroup Macau Limited (BVI), Polytree (H.K.) Co. Ltd.*, 15-cv-3443, 3:15-cv-00552, United States District Court for the District of Minnesota.
	Project:	Patent litigation involving modular mechanical and electrical connectors
	Status:	Settled
2016 to Present	Client:	Locke Lord LLP
	Case	*Denneroll Holdings Pty Limited and Denneroll Industries International Pty Limited v. ChiroDesign Group, LLC and Marie L. Webster, Individually and D/B/A ChiroDesign Group;* Civil Action No. 4:15-cv-740; United States District Court for the Southern District of, Houston Division.
	Project:	Patent litigation involving chiropractic pillows
	Status:	Settled; Infringement Expert Report, May 2016; Validity Expert Report, June 2016

2016 to Present	Client:	Mass Montes LLP
	Case:	*Logan W. Hensley vs. Michael J. Skyhar, MD.; Cayenne Medical, Inc., and DOES 1 thru 40, inclusive;* Case no. 37-2015-00005140-CU-MM-NC, Superior Court for the State of California for the County of San Diego, North County Division.
	Project:	Personal injury involving failed medical device and medical practice
	Status:	Settled

2016 to Present	Client:	Hamrick & Evans, LLP
	Case:	*Laurence Johnson vs. Raytheon Company, Systems XT, Inc. Brownco Construction Company, Inc., Power Edge Solutions, Inc. (aka PES Controls), et.al.* United States District Court for the Central District of California; Case No. 2:15-cv-00132-MWF-E.
	Project:	Personal Injury; Product Performance & Product Liability
	Status:	Settled

2015 to 2016	Client:	Nixon Peabody LLP
	Case:	*Johnstech International Corp v. JF Microtechnology SDN BHD* United States District Court for the Northern District of California; Case No. 3:14-cv-02864-JD
	Project:	Patent litigation involving semiconductor test technology
	Status:	Invalidity Expert Report, Non-Infringement Expert Report – Dec 2015; **Patent Trial Testimony – Sep 2016**. Jury Verdict.

2015	Client:	Susman Godfrey LLP
	Case:	*Bonutti Skeletal Innovations, LLC v. Globus Medical, Inc*
	Project:	Patent litigation involving spinal medical devices
	Status:	Settled

2015	Client:	Richardson, Patrick, Westbrook, & Brickman, LLC
	Case:	*Smart v. PACCAR*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled

2014 to 2018	Client:	Harris and Graves, P.A.
	Case:	*Raven N. Dineen v. Sprint Corp, Asurion Protection Services, LLC and Apple, Inc.,* District Court, Greenville Division, District of South Carolina, No. 6:16-cv-01549-MGL
	Project:	Investigation of alleged cellular telephone defect and Lithium-Ion battery breach; Personal injury (victim sustained burns) due to ignition & combustion of cell phone; Non-Destructive & Destructive Inspections
	Status:	Settled; Deposition Oct 2017; Expert Report, July 2015, July 2017;

2014 to 2019	Client:	Law Offices of David McQuade Leibowitz, P.C.
	Case:	*Ricardo Garza v. Daimler Truck of North America (DTNA), Freightliner LLC;* Texas Circuit Court, Bexar County, Texas
	Project:	Heavy Truck Crashworthiness
	Status:	Trial Testimony Sep 2019; Deposition Jul 2018; Expert Report Apr 2018; Jury Verdict;
2014	Client:	Kolisch Hartwell, P.C.
	Case:	*TMI Products, Inc. v. Rosen Entertainment Systems, L.P* United States District Court for the Central District of California; Case No. EDCV12-02263 RGK (SPx)
	Project:	Patent case involving consumer electronics & vehicle entertainment applications
	Status:	Settled; Deposition March 2014; Declaration & Report March 2014; Declaration & Rebuttal Report March 2014;
2014 to 2018	Client:	Corsiglia, McMahon, & Allard
	Case:	*Avalos v. Balt, Stanford Hospital & Clinics, et.al.*
	Project:	Personal Injury during Medical Procedure & Medical Device Product Liability; Failure analysis of micro-catheter for neurovascular treatment; embolization of a cerebral AVM during procedure at Stanford Hospital
	Status:	Settled
2014 to 2015	Client:	The Previant Law Firm, S.C.
	Case:	*Kaminski v. DongGuan, et.al.*
	Project:	Personal injury (eye damage) due to failure of consumer product (elastomeric strap tie-down); Failure analysis, material testing, and evaluation of elastomeric material components
	Status:	Settled; Expert Report, July 2014
2013 to 2015	Client:	Guajardo & Marks, LLP
	Case:	*Bertha A. Flores Individually and as Representative of the Estate of Jose Flores, et.al. v Daimler Trucks North America, LLC.* United States District Court for the Southern District of Texas, Corpus Christi Division, and is Civil Action No. 2:13-cv-87
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled, Mar 2015 Deposition, Feb 2015; Report, Oct 2014
2012 to 2014	Client:	Edwards Life Sciences; Kilpatrick, Townsend & Stockton, LLP
	Case:	*Medtronic v. Edwards* Case No. 11-CV-1650-JNE/JSM (D. Minn.)
	Project:	Medical device patent claims, infringement & invalidity
	Status:	Settled Invalidity Report Aug 2013; Non-Infringement Report Oct 2013; Deposition Oct 2013, Oct 2012

2013 to 2014	Client:	US Securities and Exchange Commission
	Case:	*Securities and Exchange Commission (SEC) v. Inteligentry, Ltd., Plasmerg, Inc., PTP Licensing, Ltd., and John P. Rohner in Civil No. 2:13-CV-00344-GMN-NJK*
	Project	Securities associated with "Plasmic Transition Process Engine" technology; Technology assessment
	Status:	Resolved
2013 to 2015	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Walker v. PACCAR, Inc;* Alabama Circuit Court, Barbour County; 06-CV-2013-900032.00
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled
2013	Client:	Retained in a metal component manufacturing technology patent litigation case.
	Case:	*Confidential*
	Project:	Metal manufacturing process patent for smart-phone and consumer electronics applications
2013 to 2015	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Lacy v. Freightliner*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled Mar 2015
2013 to 2015	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Jones vs. Daimler Truck North America (DTNA)* Alabama Circuit Court
	Project:	Heavy Truck Rollover & Crashworthiness
	Status:	Settled Nov 2015; Deposition Jan 2014
2012	Client:	Smart-phone technology patent litigation case involving embedded electro-mechanical components
	Case:	*Confidential*
	Project:	Patent issues associated with specific user-feedback technologies
	Status:	
2010 to 2015	Client:	Warren & Associates, LLC
	Case:	*Jones vs. MSE Hauling*
	Project:	Heavy Truck Rollover
	Status:	Settled Nov 2015; Deposition Jan 2014
2009 to 2014	Client:	Schwarz & Mongeluzzi; Nelson, Levine, DeLuca & Horst
	Case:	*Carrera v. Navistar*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled 2014; Deposition Feb 2013

2010	Client:	Sico, White, Hoelscher & Braugh L.L.P.
	Case:	*Ramirez v. Sterling Truck*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled; Expert Report; Deposition May 2010
2008 to 2010	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Thibadeaux vs. PACCAR*
	Project:	Heavy-Truck Rollover Accidents
	Status:	Settled; 2010.
2008 to 2010	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Price vs. Navistar*
	Project:	Heavy-Truck Rollover Accidents
	Status:	Settled; 2010.
2008 to 2009	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Martin vs. Kenworth*
	Project:	Heavy-Truck Rollover Accidents
	Status:	Settled; 2009.
2007	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Strode v. Freightliner, LLC;* Civil Action No. 02-132 Circuit Court of Greene County Alabama
	Project:	Heavy-Truck Rollover Accident
	Status:	Settled; 2007. Testified at trial.
2006	Client:	Gibson, Dunn, & Crutcher
	Case:	*Jang v. Boston Scientific Corp., et.al.* United States District Court, Central District of California; Eastern Division – Riverside; Case No: EDCV 05-00426 VAP (SGLx)
	Project:	Patent case for matters involving design features of Cardiovascular Stents.
	Status:	
2005	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Mongan vs. MACK Truck*
	Project:	Retained as fact witness in heavy truck rollover accident.
	Status:	Settled, 2005
2005	Client:	Lucas Wash Petway Tucker & Stephens, P.C.
	Case:	*Gable v. International Truck & Engine Corporation* United States District Court, Middle District of Pennsylvania; Civil Action No: 3:03-CV-01353
	Project:	Heavy-Truck Rollover Accident
	Status:	Closed; Deposition June 2005.

2004	Client:	Kenyon & Kenyon Intellectual Property Law Firm
	Case:	*Medtronic Vascular, Inc. vs. Boston Scientific Corp., et al.* C.A. No. 98-478-SLR (D-Del)
	Project:	Patent case involving Cardiovascular Stent design
	Status:	Closed; Expert Report filed;
1997	Client:	Grimaldi, Pearson,and Weyand, P.C.
	Case:	*Herbolsheimer v. Warner-Swasey* Case No. 9357487NP
	Project:	Product defect of CNC machine equipment
	Status:	Closed; Deposition.
1994	Client:	Jones, Jones, Close & Brown
	Case:	*Pioneer Chlor-Alkali Co., Inc. v. National Union Fire Insurance Co.*, United States District Court, District of Nevada, Case No. CV-S-93-276-HDM (RLH)
	Project:	Accident investigation, insurance claim.
	Status:	Closed; Deposition.
1994	Client:	Clapp, Moroney, Bellagamba, Davis and Vucinich
	Case:	*Thomas Fujisaka and Sandra Fujisaka v. Livermore Valley Unified School District*, Superior Court of the State of California In and For the County of Alameda, Case No. 700921-1
	Project:	Accident Investigation, Personal Injury
	Status:	Closed; Deposition.
1994	Client:	GEA In-House Counsel
	Case	*GEA Power Cooling Systems, Inc. v. Hyspan Precision Products*, Superior Court of the State of California for the County of San Diego, Case No. 669769
	Project:	Product Liability; Failure analysis root cause.
	Status:	Closed; Deposition.
1993	Case	*Bobbye J. Phaneuf v. Edith D. Roman*, Superior Court of the State of California County of Alameda, Case No. H - 154330-4
	Project:	Product Design.
	Status:	Closed; Deposition, Trial.
1993	Case:	*Patricia C. Barbera v. H. B. Instrument Company*, Superior Court of the State of California In and For the County of Marin, Case No. 138929
	Project:	Product Design.
	Status:	Closed; Deposition, Trial.

1990	Client:	Chevron In-House Counsel
	Case:	*Secretary of Labor v. Chevron U.S.A, et al.*, Occupational Safety and Health Review Commission, Region 9, OSHRC Docket No. 89-3125
	Project:	Accident investigation; Failure analysis root cause.
	Status:	Closed; Deposition.

Trials & IPRs:

2020	Case:	*NEXTracker vs. Solar FlexRack and Northern States Metals Co.,.* United States District Court, District of Delaware
	Status:	IPR Declaration Oct 2020;
2020	Case:	*Otter Products, LLC and Treefrog Developments, Inc. vs Fellowes, Inc.* United States District Court, Northern District of Illinois, Eastern Division.
	Status:	IPR Declarations 2-Aug 2020; 2-Dec 2020; 1-Jan 2021;
2019	Case:	*Ricardo Garza v. Daimler Truck of North America (DTNA), Freightliner LLC;* Texas Circuit Court, Bexar County, Texas
	Status:	Testified in Trial, Sep 2019
2018	Case:	*Lite-On Technology Corp v Darfon Electronics Corp,* Case No. 3:18-cv-02776, United States District Court, Northern District of California.
	Status:	IPR Declaration Dec 2018;
2018	Case:	*Rick C. Sasso, M.D., and See LLC v. Warsaw Orthopedic, Inc., Medtronic Inc., Medtronic Sofamor Danek, Inc*, Indiana State Court, Case No. 43C01-1308-PL-44.
	Status:	Testified in Patent Trial, Nov 2018
2018	Case:	*SCA Hygiene Products AB et.al., SCA Tissue North America, LLC v. Tarzana Enterprises, LLC;* United States District Court, Western District of Wisconsin, No. 3:16-cv-00728
	Status:	IPR Response Declarations, July 2018 (2), May 2018;
2018	Case:	Davidson, Davidson & Kappel LLC; ArcelorMittal Project
	Status:	IPR Declaration, Mar 2018;
2017	Case:	*Trans Technologies Company v. Hendrickson USA LLC, et.al.*, United States District Court for the Northern District of Georgia, Atlanta Division, Civil Action No. 1:16-cv-01778-AT
	Status:	IPR Declaration Aug 2017; IPR Response Declaration Feb 2018;

2017	Case:	*Lenovo (United States) Inc. v. Blackbird Tech d/b/a Blackbird Technologies*, Review of U.S. Patent No. 7,129,931;
	Status:	Deposition Feb 2018; Expert Report; IPR Declaration May 2017;
2016	Case:	*Olam West Coast, Inc. v. California Fire-Roasted LLC; Inter Partes* Review of U.S. Patent No. 6,099,882
	Status:	IPR Declarations (2), Oct 2016;
2016	Case:	*Johnstech International Corp. v. JF Microtechnology SDN BHD;* Action 14-cv-02864-JD, US Federal Court, District of Northern California
	Status:	Testified in Patent Trial, Sep 2016
2007	Case:	*Strode v. Freightliner, LLC;* Civil Action No. 02-132 Circuit Court of Greene County Alabama
	Status	Testified in Product Liability/Personal Injury case;
1995	Case:	*Bobbye J. Phaneuf v. Edith D. Roman*; Superior Court of the State of California County of Alameda, Case No. H-154330-4
	Status:	Testified in Product Liability/Personal Injury case;
1994	Case:	*Patricia C. Barbera v. H. B. Instrument Company*; Superior Court of the State of California In and For the County of Marin, Case No. 138929
	Status:	Testified in Product Liability case;

APPENDIX B - Materials Considered

- "303 Stainless Steel." Penn Stainless, 5 Dec. 2018, www.pennstainless.com/resources/product-information/stainless-grades/300-series/303-stainless-steel/.
- "Access and instruments product catalog" Medtronic, 2020, available at: https://www.medtronic.com/content/dam/covidien/library/us/en/product/hand-instruments-and-ligation/access-instrumentation-products-catalog.pdf.
- Anderson, James M., Analiz Rodriguez, and David T. Chang. "Foreign body reaction to biomaterials," in Seminars in Immunology, vol. 20, no. 2, pp. 86-100, 2008
- August 19, 2021 Conversation with Ron Bair
- "Engineering Failure Analysis, Fatigue & Mechanical Tests: DNV Labs." *DNV*, www.dnv.com/oilgas/laboratories-test-sites/engineering-failure-analysis-fatigue-tests-and-mechanical-tests-dnvgl-labs-hovik.html.,
- Anderson, Patrick L., et al. "Robot-like Dexterity without Computers and Motors: a Review of Hand-Held Laparoscopic Instruments with Wrist-like Tip Articulation." Expert Review of Medical Devices, vol. 13, no. 7, 2016, pp. 661–672., doi:10.1586/17434440.2016.1146585.
- da Vinci S and Si Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=d237e175-3fce-3844-863e-37e733afe0d6&groupId=73750789
- da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=b1b9f169-4503-9ea9-6db9-9243c28d5221&groupId=73750789
- Def.'s Ex. 135 (Defendant Intuitive Surgical Inc.'s Notice of Deposition of Plaintiff Surgical Instrument Service Company, Inc. Pursuant to Fed. R. Civ. P. 30(b)(6))
- "Expanding the Reach of Surgery," Medrobotics "Flex" brochure, available at: https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf
- "Failure Analysis Testing: Engineering Failure Analysis |." *Stress Engineering Services, Inc*, 14 Feb. 2020, www.stress.com/capabilities/materials-engineering/failure-analysis/
- "Flex Robotic System Technology: How it Works," available at: https://medrobotics.com/gateway/technology/
- "Flexible 'open architecture' instrumentation," available at: https://medrobotics.com/gateway/instruments/
- "Tungsten." *Elmet Technologies*, www.elmettechnologies.com/tungsten/.
- Center for Devices and Radiological Health. "A History of Medical Device Regulation and Oversight in the US." *U.S. Food and Drug Administration*, FDA,

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- Consolidated Class Action Complaint (ECF. No 52) (*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)
- Defendant Intuitive Surgical, Inc,'s Answer and Affirmative Defense (ECF 74) (*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)
- Plaintiff Franciscan Alliance, Inc.'s Amended Objections and Responses to Defendant's Second Set of Interrogatories to Plaintiffs (Sept. 30, 2022) (*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)
- Plaintiff Larkin's Amended Objections and Responses to Defendant's Second Set of Interrogatories to Larkin (Sept. 30, 2022) (*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)
- Plaintiff Valley Medical Center's Amended Objections and Responses to Defendant's Second Set of Interrogatories to Plaintiffs (Sept. 30, 2022) (*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)
- Plaintiff Franciscan Alliance, Inc.'s Objections and Responses to Defendant's Requests for Admissions to Plaintiff (Nov. 16, 2022) (*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)

- Plaintiff Larkin Community Hospital's Objections and Responses to Defendant's Requests for Admissions to Plaintiff (Nov. 16, 2022) (*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)
- Plaintiff Valley Medical Center's Objections and Responses to Defendant's Requests for Admissions to Plaintiff (Nov. 16, 2022) (*In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC)
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- June 15th, 2021, Deposition of Bob Overmars (with accompanying exhibits)
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- June 2nd, 2021, Deposition of Glenn Papit (with accompanying exhibits)
- June 4th, 2021, Deposition of Mark Johnson (with accompanying exhibits)
- June 7th, 2021, Deposition of Anthony McGrogan (with accompanying exhibits)
- May 14th, 2021, Deposition of Glenn Vavoso (with accompanying exhibits)
- May 24th, 2021, Deposition of Edward W. Harrich (with accompanying exhibits)
- May 26th, 2021, Deposition of Katie Scoville (with accompanying exhibits)
- May 27th, 2021, Deposition of Bob DeSantis (with accompanying exhibits)
- May 27th, 2021, Deposition of Stacey Donovan (with accompanying exhibits)
- May 7th, 2021, Deposition of Myriam Curet (with accompanying exhibits)
- June 6th, 2021, Deposition of Chris Gibson (with accompanying exhibits)
- June 14th, 2021, Deposition of Joe Morris (with accompanying exhibits)
- June 4th, 2021, Deposition of Stan Hamilton (with accompanying exhibits)
- November 8th, 2022, 30(b)(6) Deposition of Grant Duque (with accompanying exhibits)
- November 8th, 2022, 30(b)(1) Deposition of Grant Duque (with accompanying exhibits)
- November 1st, 2022, 30(b)(6) Deposition of Greg Posdal (with accompanying exhibits)
- November 1st, 2022, 30(b)(1) Deposition of Greg Posdal (with accompanying exhibits)
- October 27th, 2022, 30(b)(6) Deposition of Keith Robert Johnson (with accompanying exhibits)
- October 27th, 2022, 30(b)(1) Deposition of Keith Robert Johnson (with accompanying exhibits)

- November 4th, 2022, Deposition of Sharathchandra "Shark" Somayaji (with accompanying exhibits)
- October 27th, 2022 Deposition of Nickola Goodson (with accompanying exhibits)
- November 3rd, 2022 Deposition of Kevin May (with accompanying exhibits)
- October 6th, 2022 Deposition of Karen Wagner (with accompanying exhibits)
- February 15th, 2023 Deposition of Maxwell Meng (with accompanying exhibits)
- October 25th, 2022 Deposition of Clifton Parker (with accompanying exhibits)
- October 6th, 2022 Deposition of Disha Peswani (with accompanying exhibits)
- May 18th, 2021 Deposition of Cairo Wasfy (with accompanying exhibits)
- November 9th, 2022 30(b)(1) Deposition of Colin Morales (with accompanying exhibits)
- November 9th, 2022 30(b)(6) Deposition of Colin Morales (with accompanying exhibits)
- February 24th, 2023 Deposition of Robert Howe (with accompanying exhibits)
- May 13th, 2021 Deposition of West Gordon (with accompanying exhibits)
- May 6th, 2021 Deposition of Kevin May (with accompanying exhibits)
- June 8th, 2021 Deposition of Kevin May (with accompanying exhibits)
- May 4th, 2021 Deposition of Clifton Parker (with accompanying exhibits)
- May 11th, 2021 Deposition of Mills Vautrot (with accompanying exhibits)
- Expert Report of Dr. Joshua Sharlin dated July 26, 2021 (Rebotix)
- Expert Report of Dr. Robert Howe dated July 26, 2021 (Rebotix)
- Expert Report of Dr. Kim Parnell dated Aug. 30, 2021 (Rebotix)
- Expert Report of Dr. Robert Howe dated Dec. 2, 2022 (SIS)
- Expert Report of Dr. Amandeep Mahal dated Dec. 1, 2022
- Expert Report of Kurt Humphrey dated Dec. 2, 2022
- Expert Report of Professor Einer Elhauge dated Dec. 1, 2022
- Expert Report of Dr. Eugene Rubach dated Dec. 1, 2022
- Expert Report of Kimberly A. Trautman, MS dated Dec. 1, 2022
- Expert Report of Richard F. Bero dated Dec. 2, 2022
- Expert Report of Dr. Russel L. Lamb dated Dec. 2, 2022
- Expert Report of Philip J. Philips dated Dec. 2, 2022
- Expert Report of Jean Sargent dated Dec. 2, 2022
- Expert Report of Dr. Robert D. Howe (Aug. 20, 2021) (served in *Restore*, Civil Case No. 5:19-cv-55-TKW-MJF) and materials cited therein
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- Expert Report of Dr. Robert Howe, *In re: da Vinci Surgical Robot Antitrust Litigation*, Case No. 3:21-cv-03825-VC, dated January 18, 2023 and materials cited therein
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- Restore-00109203
- Restore-00112595
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- Restore-00132591
- Restore-00132592